IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION MDL NO. 2327

Jo Huskey and Allen Huskey,
Plaintiffs,
v. Case No. 2:12-cv-05201

Ethicon, Inc., et al.,
Defendants.

ORAL DEPOSITION OF
CHRISTINA PRAMUDJI, M.D.
Friday, April 11, 2014

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ORAL DEPOSITION OF CHRISTINA PRAMUDJI, M.D., produced as a witness at the instance of the Plaintiffs, and duly sworn, was taken in the above styled and numbered cause on Friday, April 11, 2014, from 10:06 a.m. to 4:18 p.m., before Susan Perry Miller, CSR-TX, CCR-LA, CSR-CA, CLR, CRR, RDR, Notary Public in and for the State of Texas, reported via Machine Shorthand with Realtime Computer Translation and Interactive Realtime Technology, at the Westin Memorial City, 945 Gessner Road, Houston, Texas pursuant to the Federal Rules of Civil Procedure.

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ORAL DEPOSITION OF

CHRISTINA PRAMUDJI, M.D., APRIL 11, 2014

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PRELIMINARY PROCEEDINGS

(Friday, April 11, 2014, 10:06 a.m.)

(Witness sworn by the reporter.)

PROCEEDINGS

CHRISTINA PRAMUDJI, M.D.,

having taken an oath to tell the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

EXAMINATION

BY MS. KIRKPATRICK:

Q. Good morning, Dr. Pramudji. Can you state your name and your address for the record, please?

A. Christina Pramudji, M.D., 2 Lorrielake Lane, Houston, Texas 77024.

Q. And where are you currently employed?

A. Texas Oncology, Texas Urology Specialists.

Q. Okay. And is that here in Houston?

A. Yes.

Q. Okay. Now, Dr. Pramudji, you've been deposed before, correct?

A. Yes.

Q. And how many times have you been deposed?

A. In this particular litigation or mesh litigation, twice.

Q. Okay.

A. With Schubert --

Q. Do you remember what case?

A. The Schubert case and the Lewis case.

Q. And do you know where the Schubert case was based or out of, what state?

A. Missouri.

Q. And the Lewis case?

A. It was an MDL case.

Q. And you understand that you're here today in connection with a case that is in the MDL, correct?

A. Yes.

Q. And it's against Ethicon.

A. Yes.

Q. Okay. During the course of the day, I'm going to be asking you a series of

questions. If you can't hear me or you don't understand what I'm asking, please just let me know and I'm happy to rephrase it. If you do go ahead and answer, I'll just assume that you understood what it was that I was looking for.

If you need to take a break, stretch your legs, use the ladies' room, please, just let me know. This is not an endurance test so if you need a little bit of a break, that's not an issue at all.

Before we get started today, I'm going to mark a couple of exhibits.

(Whereupon, Exhibit Pramudji-1, Notice of Deposition and Document Requests, was marked for identification.)

BY MS. KIRKPATRICK:

Q. Marked as Exhibit 1 is the notice of deposition, and let me show that to you. Have you seen that document before?

A. Yes.

Q. Okay.

(Whereupon, Exhibit Pramudji-2, Expert Report of Christina Pramudji,

M.D., was marked for identification.)

BY MS. KIRKPATRICK:

Q. And I'm going to show now what's been marked as Deposition Exhibit 2. Can you identify that for me?

A. That's my expert report in relation to this case.

Q. Okay. You want to take a quick look through and make sure that, at least at a quick glance, that that's a complete copy?

(Witness reviews document(s).)

A. Yes, it is.

(Whereupon, Exhibit Pramudji-3, Report of IME on Jo Huskey, was marked for identification.)

BY MS. KIRKPATRICK:

Q. Okay. And then I'm going to show you what's been marked as Deposition Exhibit 3 and ask you what that is.

A. That is the report of my IME for Mrs. Huskey.

Q. Okay. We'll be marking some more exhibits throughout the day, but these are ones that we will refer to often.

MR. SNELL: For the record, there were urodynamics that were also sent over.

MS. KIRKPATRICK: Yes, we're going to be marking those later. Thank you.

BY MS. KIRKPATRICK:

Q. Okay. You just testified that you gave testimony previously in the Lewis case in the MDL. Is that right?

A. That's correct.

Q. And what kind of device did Ms. Lewis have?

A. She had a retropubic TDT.

Q. And you also testified that you had been deposed in the Schubert case in Missouri. What kind of device did Ms. Schubert have?

A. She had a Prolift.

Q. And in the Lewis case you gave deposition testimony. Is that correct?

A. Yes.

Q. But you did not testify at trial in that matter?

A. That's correct.

Q. Have you ever testified at trial in any mesh-related cases?

A. Not as of yet.

Q. Okay. And it's my understanding from having reviewed your deposition in the Lewis case that you set forth a number of general opinions concerning Ethicon and concerning the TVT line of products. Is that right?

A. Yes.

Q. Do you recall those opinions in this case as well?

A. Yes.

Q. What I'd like to do is, I don't want to have to go through and redepose you on the same things that you've been deposed before, so let me ask you this way: Is there anything that you testified to in the Lewis deposition concerning Ethicon or concerning TVT, the substance of these issues, that you wish to change or amend or alter at any point?

A. No.

Q. Okay. So the opinions that you espoused in that particular deposition remain current today?
A. Yes.
Q. And you've incorporated them into your opinions in Ms. Huskey's case as well?
A. Correct.
Q. Okay. In addition to your mesh-related depositions, have you given depositions in any other kind of case?
A. Yes, I have.
Q. Okay. And what are those?
A. When I was in residency, I was deposed as a resident who placed an endotracheal tube on a patient as a fact witness.
Q. Uh-huh. And that was not expert testimony?
A. No.
Q. And were you a defendant in that lawsuit?
A. No.
Q. Was it a medical malpractice lawsuit?

A. Yes.
Q. Okay. Any other testimony that you've given?
A. Yes.
Q. Okay. And what's that?
A. I was a defendant in a lawsuit in -- approximately 10 years ago, a patient of my partner's who expired unexpectedly, and I was the physician on call; and that case was dropped against -- against me and against my partner.
Q. Okay.
A. And they only sued the hospital.
Q. Okay. And what was -- was the patient an inpatient at the time?
A. Yes.
Q. And what was the condition that he or she --
A. He was in the hospital for a kidney stone and subsequently was found to have a renal mass as well.
Q. Okay. And did you give your testimony in that case?
A. I was deposed.

Q. You were deposed.
A. Yes.
Q. Okay. And that was as a defendant?
A. As a defendant.
Q. Okay. Any other cases?
A. And there was one other case where my group was the defendant, and I was the representative of the group in a patient that was in the hospital with gross hematuria and had a bladder rupture.
Q. Okay.
A. And that case was dropped against the group.
Q. And you gave deposition testimony there?
A. Yes, I did.
Q. Okay. Any other cases where you or your practice was a defendant to a lawsuit?
A. No.
Q. Okay. Any other cases in which you gave a deposition?
A. No.

Q. Are these mesh cases that you're testifying on behalf of Ethicon, are those the first cases where you've served as an expert witness?
A. Yes.
Oh, I'm sorry, no. There is another case where I served as an expert witness for a drugstore company. It was a patient -- yeah, I guess a person, a customer of theirs, who fell in their store and claimed that the fall caused urinary incontinence; and I was not deposed. I just wrote an expert report or expert opinion.
Q. On behalf of the drugstore?
A. Correct.
Q. And your opinion in that case --
A. Was that the fall did not cause the incontinence. She had that before the fall.
Q. Okay. Is there anything else?
A. That's all.
Q. Okay. So you understand that in Ms. Huskey's case, you're serving as an expert witness for Ethicon. Is that right?

A. Yes.
Q. But in addition to serving as an expert in the litigation and the -- let me make sure I get this right -- Schubert, Lewis and Huskey cases, you've also done other work for Ethicon. Isn't that right?
A. That's correct.
Q. Okay. So can you tell me what it is, what type of work you have done for Ethicon outside of the expert witness arena?
A. Sure. I have done primarily preceptorship work, teaching other physicians the techniques with Prolift, TVT-O, Solyx -- not Solyx -- TVT-Secur and Prolift+M. I have done some advisory panels, for which I was reimbursed. And I have helped moderate at meetings and at their booth at the AUA.
Q. And in each of these positions, you were compensated for the work that you did for Ethicon?
A. Yes, I was.
Q. And how much -- were you compensated on an hourly basis?
A. They typically do it as a

half-day basis.
Q. Okay. And how much were you reimbursed for a half day?
A. $1,500.
Q. Okay. And how much are you compensated in this litigation for the work that you do for Ethicon?
A. $600 per hour or $700 per hour for deposition and trial.
Q. Okay. When did you begin doing work for Ethicon?
A. Around 2005.
Q. And how did you come to work with Ethicon regarding their mesh products?
A. My senior partner, Dr. Anhalt, had been a preceptor for Ethicon for the TVT retropubic. He was the first person in Houston to do that procedure, and so he had a relationship with Ethicon. And we operate together quite a bit so he recommended to them that they start to involve me as well, and we would do the preceptorships together.
Q. Okay.
A. Most of the advisory boards and

the preceptorships, we would do together.
Q. And does that continue to this day, that you do most of that work with your partner?
MR. SNELL: Form.
A. No. We don't have -- we don't do preceptorships anymore.
BY MS. KIRKPATRICK:
Q. You don't do them at all?
A. No. They haven't had any new products that they need preceptors for.
Q. Okay. So I want to just go through a list of work you may have done with Ethicon and just establish some basic facts about it. You testified that you've been parts of advisory boards or advisory panels? Is that right?
A. Yes.
Q. And was that compensated at that rate of $1500 a half day?
A. Yes.
Q. What advisory boards or panels did you work on for Ethicon?
A. I can only remember a couple off

the top of my head. There was one where they wanted to hear from urologists, it was specifically urologists that went to their headquarters in New Jersey, and they were getting our feedback on the mesh procedures and future directions that they might want to take.
Q. Uh-huh.
A. And I remember one that was specifically just Dr. Anhalt and I and they had some sort of secret new procedures that they were kind of just throwing -- you know, getting our feedback on, getting our opinion on.
Q. Okay. Do you remember any others?
A. I can't remember any others off the top of my head.
Q. Okay. Do you remember just generally how many advisory boards you'd have served on for Ethicon, the ballpark figure?
A. I feel like there may have been one or two more than what I can remember.
Q. Okay. So it's safe to say

somewhere between maybe two and five?
A. Yes.
Q. Okay. You also testified that you were a sponsored speaker or somebody who's addressed or spoken on behalf of Ethicon at meetings? Is that right?
A. Yes.
Q. Okay. And can you tell me which meetings you spoke about -- or, excuse me, strike that.
Can you tell me which meetings you represented Ethicon at?
MR. SNELL: Form. Go ahead.
A. AUA in Anaheim; that would have been around -- let's see -- 2007, I believe. I helped give some talks about cases at the AUA booth.
BY MS. KIRKPATRICK:
Q. Uh-huh.
A. And then at one of the last -- I think the last TVT summit, which was in Sonoma, I moderated a -- what did they call it -- it was sort of a case discussion where one physician would present cases and I would

moderate the questions and, you know, if people wanted to ask questions and bring up certain issues that we would talk about.
Q. Did these involve SUI products, POP products or both?
A. Both.
Q. Okay. So you gave me two that you remember. Are there any others? Can you give me a ballpark of how many times you served as a compensated speaker for --
A. That's all I can remember for that.
Q. Okay. You also said that you did preceptorship work on Prolift, Prolift Plus and TVT-O, TVT Secur. Is that right?
A. Yes.
Q. Have you ever done it for the TVT Classic?
A. No.
Q. How many times have you done preceptorships for the TVT-O?
A. It would have been in conjunction with the Prolift cases. They would not have been separate preceptorships only for that.

Q. Okay. And do you know about how many times?
A. Maybe somewhere between five and 10, I would say.
Q. Okay. Have you ever presented to the sales force or any sales representatives at Ethicon?
A. No.
Q. Have you ever performed any product research for Ethicon?
A. No.
Q. Have you ever received any grant money from Ethicon to perform research or do any kind of medical reviews for them?
A. No.
Q. Have you ever been asked to provide any information or input into publications that Ethicon is doing?
A. No.
Q. Have you ever participated in any design validation projects?
A. No.
Q. So in other -- in addition to the things that we've spoken about, is there

anything else that you have done for Ethicon outside of the expert arena between 2005, when you started working with them, through the present?
A. Not that I can recall.
Q. Can you tell me how much money to date you have been paid by Ethicon for your non-expert work?
A. I don't remember that number. That was presented in the prior case, so that data is available.
Q. Okay. Since that time, have you been compensated by Ethicon for any non-expert work?
A. No.
Q. So the numbers that you gave in the Lewis case would be current through today?
A. That's correct.
Q. Okay. When did you become retained or when did Ethicon retain you to work as an expert in pelvic mesh litigation?
A. They started talking to me about a year and a half ago, is the initial

meeting, and then I officially was retained last summer, 2013.

Q. So retained in the summer of 2013.

And who approached you about working with Ethicon as an expert?

A. The first person was Michael Brown.

Q. And who else have you spoken to concerning your work with -- as an expert witness for Ethicon?

MR. SNELL: In any -- just so I understand, in any kind of shape, form? Depositions, trial?

MS. KIRKPATRICK: Yeah, just who have you spoken to.

MR. SNELL: Okay.

A. Well, of course, Burt Snell, Christy Brown -- I mean Christy Jones. Where did that come from? Christy Jones.

BY MS. KIRKPATRICK:

Q. Don't tell her that, okay?

A. I'm sorry.

And when I was in Charleston,

West Virginia, I met several attorneys but I don't remember all their names.

Q. Okay. But you've primarily worked with Mr. Snell and Ms. Jones on these cases. Is that right?

A. Yes. Oh, I did do one deposition prep with Anita Modak-Truran.

MR. SNELL: Good enough.

BY MS. KIRKPATRICK:

Q. Okay. Anyone else?

A. No, that's all.

Q. Okay. And can you tell me, were the figures that you relayed before in your Lewis testimony current as of that time on the amount of money that you've been paid for expert services by Ethicon?

A. Yes.

Q. Okay. Since the time of your Lewis deposition, how much money have you been paid by Ethicon for your expert services?

A. I would have to look at the exact number. I can give you a ballpark. It was around $50,000.

Q. Okay. So your best estimate, sitting here, is that you've been paid another $50,000?

A. Correct.

Q. Is there any amount that you've billed that's still owing to date?

A. No.

Q. You've billed for all of your services, except, I'm assuming, for the deposition here today, and you've been compensated for everything that you have done?

A. No. I haven't billed for my Huskey -- anything related to Huskey as of yet.

Q. Okay. How much time have you spent on Ms. Huskey's case, approximately?

A. Specifically on Ms. Huskey's case, about 50 hours.

Q. Can you tell me what you did in that 50 hours, just a general breakdown of the type of work that you did?

A. Yeah. I reviewed the medical records, the depositions, write the report;

the IME, writing the report for that. Reviewing the literature, preparing for today.

Q. Okay. Let me just ask you briefly about the literature. In your previous testimony in Lewis and in the expert report that you gave there, you had opinions about what the literature reflected concerning TVT devices.

A. Uh-huh.

Q. Is there any other literature that you are relying on in this case in addition to what you discussed or what you identified in the Lewis case?

A. Yes. There are a couple of papers that have -- that I've added.

Q. Okay. Can you tell me which those are?

A. I'd have to go through it and look.

Q. Yeah, whatever you need to look at is fine.

A. And I may -- there may be some that I give you in error because there's so

many papers, and it's hard to remember which ones are new and which ones...
(Witness reviews document(s).)
A. This one's new.
(Witness tenders document.)
(Whereupon, Exhibit Pramudji-4, "Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis", was marked for identification.)
A. You know, I think without going through my report, it's hard to really remember which ones are which.
(Witness tenders document.)
(Whereupon, Exhibit Pramudji-5, "Randomized Trial of Tension-Free Vaginal Tape and Tension-Free Vaginal Tape-Obturator for Urodynamic Stress Incontinence in Women", was marked for identification.)
BY MS. KIRKPATRICK:
Q. Thanks.
A. Those I know.
MR. SNELL: Just so I'm clear,

Counsel, are you asking in addition to the ones that she has in her report, anything beyond that?
MS. KIRKPATRICK: What I'm trying to understand is -- you know, we kind of agreed that we're not going to rehash old ground with Lewis, so I don't want to ask about all of the literature out there.
I'm asking Dr. Pramudji if she can identify for me what specifically she's relying on here that wasn't covered in Lewis so we can narrow the focus of what we're talking about today.
(Whereupon, Exhibit Pramudji-6, "Polypropylene mesh: evidence for lack of carcinogenicity", was marked for identification.)
MR. SNELL: Her report has additions, I know that for a fact. What I'm trying to understand is you mean beyond those obvious additions in her report, or --
MS. KIRKPATRICK: Right. What I don't want to do --

We can go off the record here.
(Recess, 10:28 a.m. to 10:34 a.m.)
BY MS. KIRKPATRICK:
Q. Okay, Dr. Pramudji. I'm not trying to give you a memory test here. What I'm really just looking for are the primary documents that you can recall that you've relied on, the primarily medical literature that you relied on for your opinions in this TVT-O case versus the TVT case that you identified or that you used in Ms. Lewis's case.
A. Okay.
Q. And I understand that you have things on your reliance list and cited in your report and that you intend to rely on those.
A. Yes. These are a couple others that I don't believe are on the report list that I looked at since that deposition.
Q. Okay. Let me take a look at those.
A. This one's not specifically about TVT-O, but it's got some useful information

in it.
(Whereupon, Exhibit Pramudji-7, "Long-Term Results of Burch Colposuspension", was marked for identification.)
BY MS. KIRKPATRICK:
Q. Okay. Anything else?
(Witness tenders document.)
(Whereupon, Exhibit Pramudji-8, "Five-year Results of a Randomized Trial Comparing Retropubic and Transobturator Midurethral Slings for Stress Incontinence", was marked for identification.)
BY MS. KIRKPATRICK:
Q. And if you come across anything later, you can certainly let me know.
Okay. Let me just identify these for the record. Exhibit 4 is a medical article entitled, "Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis."
Exhibit 5 is a medical article from the Journal of Urology entitled

"Randomized Trial of Tension-Free Vaginal Tape and Tension-Free Vaginal Tape-Obturator for Urodynamic Stress Incontinence in Women."

MR. SNELL: Who is the author on that?

MS. KIRKPATRICK: Roderick Teo.

Exhibit 6 is from the International Journal of Urogynecology and Pamela Moalli, "Polypropylene mesh: evidence for lack of carcinogenicity," there we go, got it out.

Exhibit 7 is from Gynecologic and Obstetric Investigation. It's entitled, "Long-Term Results of Burch Colposuspension."

And Exhibit 8 is from the European Association of Urology, "Five-year Results of a Randomized Trial Comparing Retropubic and Transobturator Midurethral Slings for Stress Incontinence."

BY MS. KIRKPATRICK:

Q. And those are articles that you're relying on for your opinions in

Ms. Huskey's case. Is that right?

A. That's correct.

Q. Okay. Going back to your work specifically for Ethicon, by the time you were retained as an expert for Ethicon in the summer of 2013, you had worked for them for about eight years prior to that in the various roles that we have discussed, correct?

A. That's correct.

Q. And you had been compensated a significant sum of money for your work with Ethicon prior to your retention as an expert witness in the summer of 2013.

MR. SNELL: Form. Okay. Go ahead.

A. Well, define "significant." I mean, do you have a specific number in mind that you're referring to?

BY MS. KIRKPATRICK:

Q. I don't. We can take significant out if you'd like. You've been compensated the amount that you identified --

A. Yes.

Q. -- in your Lewis testimony?

A. Okay.

Q. And you haven't been compensated beyond that for any other work?

A. Correct, yes.

Q. Okay, thank you. What specifically were you asked to do in Ms. Huskey's case?

A. Well, first I was asked to review the basic medical records, the most pertinent medical records and decide if I felt that I would support the position of Ethicon in this case.

And then I was asked to provide my opinion based on all the medical records and depositions that had been taken up to that point to formulate my opinions in regard to that case.

Q. And do you know when you were first contacted by Ethicon or their lawyers about Ms. Huskey's case?

A. Yes. It was mid February.

Q. Mid February of 2014?

A. Correct.

Q. Okay. And what did Ethicon provide you with as of mid February 2014 to allow you to make a decision about whether you supported the position of Ethicon in this particular case?

A. I can't remember exactly. I know it included the operative reports. It included Dr. Byrkit's initial evaluation and surgery discussion, Ms. Huskey's deposition and Dr. Byrkit's deposition. I can't remember. There was more, but I can't remember everything.

Q. Okay. Did you look at any medical records from Dr. Siddique?

A. Yes. Well, the operative reports, and I believe some of the office visits from that.

Q. What other medical records do you recall reviewing at the outset to make the initial decision about whether you could support Ethicon's opinions in this case?

MR. SNELL: Form.

Go ahead.

A. I can't recall.

BY MS. KIRKPATRICK:
Q. Okay. And when did you make the decision that you were willing to serve as an expert witness for Ethicon in this matter?
A. After I reviewed those records.
Q. Okay. And how long did that take you?
A. About a day.
Q. Do you remember who at Ethicon you contacted to say that, yes, you were willing to serve as an expert witness?
A. Mr. Snell.
Q. And was Mr. Snell the person who contacted you in the first instance to ask --
A. Yes.
Q. -- if you would consider being an expert?
Have you discussed Ms. Huskey's case with anybody else at Ethicon besides Mr. Snell?
A. No.
Q. Did you tell Mr. Snell what information you would want to review before making a decision whether to serve as an

expert witness in this case?
A. Yes.
Q. And did he provide all of that information to you?
A. Yes, he did.
Q. Did he provide any other information to you that he believed would be helpful in formulating your opinion in this case?
A. I'm not sure, but I would think so, because there's a very -- I mean, just numerous medical records and depositions. There's several things.
Q. Did he provide you with any literature?
A. Yes, he did.
Q. Okay. And what literature did he provide you with?
A. Well, he actually helped me with almost all the literature. It's very comprehensive.
Q. Did you do an independent literature review in connection with Ms. Huskey's case to determine what

literature you believed was relevant to your opinions in this case?
A. No, I did not.
Q. And that was -- the literature that you relied on was the literature that was provided to you by Mr. Snell?
A. Yes.
Q. Okay. Did Mr. Snell provide you -- after Mr. Snell had provided medical literature to you, did you go out and research or look for any other types of medical literature to answer any other questions that you may have concerning the issues in this case?
A. Well, I'm always reviewing the literature. I can't say I did a specific search, but I'm always scanning for new information regarding sling and mesh cases. I haven't really found anything else that hasn't been included that I feel like is relevant to my opinions, but I'm always reviewing the literature, looking for all the information that I can regarding the sling and mesh cases.

Q. Okay. About how many -- let's take a look at your expert report, which was marked, I think, as Exhibit 2 in this case.
A. Uh-huh.
Q. And marked as Exhibit B to this is a -- one, two, three, four, five, six, seven, eight -- somewhere around 20 pages, give or take a few pages, that are listings of medical literature. Is that correct?
A. Yes.
Q. And this is the medical literature that you've identified about your reliance material in addition to the specific medical articles that you've cited in your report itself, correct?
A. Yes. Yes.
Q. And Mr. Snell provided you with each of these articles?
A. Yes.
Q. And did you read each of these articles?
A. At least I read the abstract on each of them and skimmed through all of them.
Q. And this is -- there's nothing on

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this list, apart from the medical articles -- well, I'm sorry, that's a bad question.

In addition to that, there are some Ethicon documents that you have identified on here, patient brochures and some other information at the end of the list. Do you see that?

A. Yes. The IFU.

Q. It includes the IFU, there's slide decks.

A. Yes.

Q. There's a whole bunch of videos.

A. Correct.

Q. Is that all information that Mr. Snell provided to you specifically in connection with this case?

A. Yes.

Q. Did you do any kind of independent research into any other source of information concerning Ethicon or the company at all, or did you rely solely on what Mr. Snell had provided to you?

MR. SNELL: Object to form.

A. You know, just looking back at

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some of my own materials that I had, but they were already on the list, yeah.

BY MS. KIRKPATRICK:

Q. Okay. So it's fair to say that everything that is identified in the last three pages here, which are the Ethicon documents, they're all documents that were provided to you by Mr. Snell in connection with this litigation?

A. Yes.

Q. Okay. Now, do you believe that it's important, as a physician, to gather as much information as you can about a patient before making a determination of the cause of a medical condition?

A. Yes.

Q. Okay. And you would consider all of the possible causes of a medical condition when reviewing someone's medical records, correct?

A. Yes.

Q. That's no substitute, though, for actually test- -- for actually talking to a patient and getting a firsthand account of

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what their medical condition is, correct?

A. Well, yes. I mean, the best thing is to take it all in toto; their history, the records that you have, listening to the patient, and of course, examining the patient.

Q. Okay. When did you ask to perform an IME of Ms. Huskey in this case?

A. I can't remember when.

Q. Did you feel confident generating an expert report in this matter without having had the opportunity to speak with Ms. Huskey and examine her?

A. Yes.

Q. Okay.

A. And I did note in my expert report that I would supplement this, once I did the IME.

Q. And you did do that and you provided us with that this week. Is that right?

A. Yes.

Q. Did the IME change your opinions at all?

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A. No.

Q. How many times have you met with Mr. Snell to prepare for your expert reports and testimony in Ms. Huskey's case?

A. Well, we met in person yesterday and we spoke on the phone a handful of times.

Q. How long did you meet for yesterday?

A. Four hours.

Q. Four hours, okay. You performed the IME of Ms. Huskey on what date?

A. Last Friday, April 4th.

Q. April 4th.

A. Yes.

Q. Okay. And then you issued the report that we've identified as Exhibit 3 on what day?

A. I issued this I believe on April 9th.

Q. And that was Wednesday of this week. Is that right?

A. Correct.

Q. Between Ms. Huskey's IME with you on Friday, April 4th, and the time that you

issued your written report identified as Exhibit 3, how many times did you talk to Mr. Snell?

A. Once.

Q. And how long was that for?

A. 15 minutes.

Q. Who wrote your IME?

A. I did.

Q. Did you have any input from anyone else?

MR. SNELL: Hold on. You're not answering that. We had an agreement and I didn't ask your experts about the drafting process.

MS. KIRKPATRICK: No, I think I can ask her if anyone besides -- you're correct, I shouldn't be asking her if it included you, but I think I can ask her if there's anybody else out there who had input into the report and I think you did that in Dr. Steege's deposition regarding Dr. Carey. So you're right, it's a bad question.

MR. SNELL: Okay. So she's

asking you besides any discussions with me, she's talking about any other doctors or any other folks.

THE WITNESS: Okay.

BY MS. KIRKPATRICK:

Q. So yes, let me pull that back.

A. I understand. Okay.

Q. Is there anyone besides Mr. Snell that you talked to or got input on for the IME itself?

A. No.

Q. Okay. Did you draft your expert report that is identified as Exhibit 2 in this case?

A. Yes, I did.

Q. And is that all your original work product?

A. Yes.

Q. How long did it take you to draft that?

A. A long time. A lot of it was also carryover from the Lewis case, the general opinions.

Q. And did you draft your opinions

and expert report in the Lewis case yourself?

A. Yes.

Q. Did you work with any other experts to prepare or discuss Ms. Huskey's case?

A. No.

Q. Do you know who is serving as an expert witness for Ethicon besides yourself?

A. I know Burt's told me, but I can't remember right now.

Q. So besides the communications that you've had with the lawyers for Ethicon, you haven't discussed this case with any other experts or any other physicians or anyone else?

A. No.

Q. Okay. Now, sitting here today, what we've marked as Exhibit 2 and Exhibit 3 contains all of the opinions that you intend to offer in Ms. Huskey's case, correct?

A. Those are my primary opinions. There may be some new -- if there's some new information that comes out, there may be new opinions that I would offer at the time of

trial.

Q. Sitting here today, do you recall any opinions as of whatever date -- April 11th, I think it is -- in addition to what has been set forth in your expert report marked as Exhibit 2 and in your IME marked as Exhibit 3?

A. No.

Q. You haven't discussed any new opinions or reached any new opinions to date. Is that right?

A. That's correct.

Q. Okay. If you can take a look at Exhibit 1, which is your notice of deposition.

A. Sure.

Q. And I think you testified that you saw this before today?

A. Yes.

Q. Okay. When did you see it?

A. I don't recall.

Q. And attached to the notice of deposition is a Schedule A that identifies a list of things that we asked you to bring

with you today to the deposition. Is that right?
A. Uh-huh.
Q. And -- oh, I think they're gone. Looks like you brought about five boxes worth materials?
A. Correct.
Q. Okay. I just want to make sure that I have this correct for the record. That material that you brought today includes all of the materials that you relied on and that were identified in your Lewis case, correct?
A. Hmm...
MR. SNELL: I'm going to object to that. Object to the form.
A. I believe so.
BY MS. KIRKPATRICK:
Q. Okay. And in addition to that, you've brought information with you that's relevant to Ms. Huskey's case specifically. Is that right?
A. Yes.
Q. Can you identify for the record

what it is that you brought with you today in response to Schedule A that relates to Ms. Huskey's case?
A. The medical records and the depositions, the reports, the IME report. I believe that's it, that's all.
Q. Okay. Let's talk about the depositions. I know from looking through the box earlier, which I appreciate your letting me do that, that you have a number of reports -- excuse me, a number of depositions that were taken of both fact and expert witnesses in Ms. Huskey's case with you.
A. Yes.
Q. Can you just go through those and identify them for the record, which ones they are that you have reviewed in connection with your testimony and opinions?
A. Uh-huh. Yes.
MR. SNELL: Do you want her to actually pull the --
A. Do you want me to just look at the list?
BY MS. KIRKPATRICK:

Q. Yeah, I mean, you can pull them. I know there are some depositions that you've looked at that were not identified.
(Discussion off the record.)
MR. SNELL: I thought there was another binder.
A. Dr. Byrkit; Sohail Siddique, S-I-D-D-I-Q-U-E, first name Sohail. Dr. Elizabeth Mueller, M-U-E-L-L-E-R. Nancy Davidson. John Steege, S-T-E-E-G-E. I skimmed Dr. Colleen Fitzgerald. Dr. Vladimir --
Q. Iakovlev?
A. -- Iakovlev, I-A-K-O-V-L-E-V. Jo Huskey. Did I say Gretchen Dean already?
Dr. Dele Ogunleye, D-E-L-E, last name O-G-U-N-L-E-Y-E. Dr. Blaivas, B-L-A-I-V-A-S. Dr. Bruce Rosenzweig, R-O-S-E-N-Z-W-E-I-G.
Q. Is there one right under that too?
A. No, that's Blaivas. I got extra back.
Q. Okay. And did you review all of

these depositions in connection with your testimony here today?
A. Yes, the ones that I said. There were some that I didn't review in detail.
Q. Okay. I believe you said you didn't review Dr. Fitzgerald in detail?
A. Right.
Q. Which other ones did you not review in detail?
A. Dr. Rominger, Dr. Schoenig, Ruth Teel, Terry Ward and Brian Yocks and Allen Huskey, James Harms, Michelle Irvin.
Q. Okay. So those are depositions that you had available to you but you just skimmed because you didn't think that they were central to your opinions in the case?
A. Correct.
Q. Do you -- outside of your connection in this case, do you know any of the physicians that have treated Ms. Huskey?
A. No.
Q. Do you know any of the physicians who have offered expert opinions on behalf of Ms. Huskey?

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A. No.
Q. Do you know any of them by reputation?
A. Yes.
Q. Who do you know by reputation?
A. Jerry Blaivas.
Q. And how do you know Dr. Blaivas by reputation?
A. From AUA courses and from the literature.
Q. And do you consider him an expert on the mesh complications and urology issues?
A. No.
Q. You do not. Why not?
A. I consider him an expert in urology, female urology, but he doesn't have a lot of experience with implanting mesh.
Q. But you agree he's got a lot of experience in explanting mesh, don't you?
A. In incontinence treatment.
Q. In explanting mesh specifically?
A. I don't know how much experience he has with that.
Q. Did you read his deposition?

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A. I did.
Q. Okay. Do you remember how many he said?
A. I don't remember what he said.
Q. How many meshes have you removed?
A. I would say I've probably done 10 to 20 explants, like complete explants. And then I've done multiple revisions or partial removals.
Q. And how -- are those SUI related specifically?
A. No. They could be pelvic organ prolapse or SUI.
Q. Okay. And I think you started to say innumerable and then you went to multiple partial revisions.
A. Yeah.
Q. Can you give me a ballpark on those?
A. Sure. I'm going to say probably around 50 to 60, somewhere in that range.
Q. And do you think that work in removing SUI devices qualifies you to testify as an expert here on issues related to the

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removal of Ms. Huskey's mesh?
MR. SNELL: Form.
Go ahead.
A. I think, yes, that and my experience with mesh in general.
BY MS. KIRKPATRICK:
Q. Okay.
A. Over a thousand slings and Prolift patients.
Q. So you've put mesh in about a thousand times. Is that right?
A. 15 to -- 1500 to 2000, somewhere in there.
Q. Okay. And you've removed mesh from not quite a hundred patients. Is that right?
A. Uh-huh.
Q. And you also know that you've had patients who have had their mesh removed by other physicians, correct?
A. Yes.
Q. And how many patients of yours have had their mesh removed by other physicians?

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A. I know of two.
Q. Okay. You know of two specifically?
A. Yes.
Q. But you'd agree with me there's probably more than that?
MR. SNELL: Form.
A. I don't know.
BY MS. KIRKPATRICK:
Q. Okay. In addition to Dr. Blaivas, are there any of the other experts that you know by reputation?
A. Elizabeth Mueller. Well, she's not an expert, she was a fact witness.
Q. Okay. And what do you know about Dr. Mueller?
A. She's involved in a lot of studies related to incontinence and prolapse.
Q. Okay. Anyone else?
A. No.
Q. Okay. Let's try to move pretty quickly through Schedule A, if we can.
A. Yes.
Q. We asked you to bring records

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related to your fees, billing or time spent. I think you told me already you haven't generated a bill related to Ms. Huskey's case. Is that right?

A. That's correct.

MS. KIRKPATRICK: Burt, when that's generated for Ms. Huskey's case --

MR. SNELL: I'll give it to you, of course.

BY MS. KIRKPATRICK:

Q. All right. We asked you to bring an updated copy of your CV. Is the copy that was provided with your expert deposition the most up-to-date copy of that CV?

A. Yes, it is.

Q. I'll go through that in a minute with you.

We asked you to bring with you all documents, including but not limited to videotapes, recordings, databases, whether preliminary or final, prepared by or at your direction in connection with your expected testimony or in connection with the development of an opinion or belief, or an

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assessment or determination of facts, relating to this or any other pelvic mesh cases.

Did you bring anything else responsive to that?

A. Just -- the boxes that I brought include everything.

Q. Is there any specific information that you have that is responsive to the requests in Schedule A that you did not bring with you today?

A. On this whole list?

Q. Yeah. I just want to see if there's anything that wasn't provided.

A. Okay. I'm trying to think. So I believe we are going to -- you know, I know at the last deposition he asked for the records of compensation from Ethicon and you were going to be able to get that from him, so everything else is comprehensive.

Q. And what you're talking about there is that after your Lewis deposition, you provided records to Mr. Kountze concerning the amount of money that you've

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been compensated by Ethicon, correct?

A. Yes. He wanted the consulting agreements and the record of compensation so I provided everything that I had related to that.

Q. So everything that Mr. Kountze has brings us up to date and current on that request?

A. That's correct.

MR. SNELL: And I'll just make a note for the record it was provided to MDL liaison counsel as well. It was provided to multiple people.

MS. KIRKPATRICK: I just want to know where to get it. So I can get it from --

MR. SNELL: MDL liaison counsel has the payments, all of that stuff.

MS. KIRKPATRICK: MDL liaison counsel or --

MR. SNELL: Jeff Kuntz, Bryan Aylstock, they were all sent that.

MS. KIRKPATRICK: Okay. So the leads for Ethicon specifically had them,

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that's great.

MR. SNELL: Yeah. Also Dr. Pramudji produced documents, communications between her and Ethicon that were --

THE WITNESS: Oh, that's right, all those emails. There weren't that many, but I had to go through them.

MR. SNELL: That production was made on the MDL plaintiffs' counsel as well.

BY MS. KIRKPATRICK:

Q. Okay. And that was a production that you made in connection with the Lewis case, correct?

A. Correct.

Q. Is there anything else that you have generated, any other communications you have had with Ethicon outside of your work as an expert witness?

A. No.

Q. There's no other communications?

A. No.

Q. There's no other emails?

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A. No.
Q. There's no other billings or anything like that?
A. That's correct.
Q. So what I can get from them will be the complete copy?
A. Yes.
Q. Okay, great. Is there anything else that you did not bring with you today --
A. No.
Q. -- that would be responsive to this subpoena?
Okay. Is there anything here -- well, we can talk about that off the record.
Okay, Dr. Pramudji. You are a urologist, correct?
A. Correct.
Q. And there's a difference between being a urologist and a urogynecologist, isn't there?
A. Yes, there is.
Q. Can you describe the difference for me, please?
A. Yes. A urologist has six years

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of surgical training centered around the urinary tract, and there is also pelvic floor training in that as well. We do major surgery such as bladder removal, reconstruction, kidney removal, very detailed reconstruction of the urinary tract.
Now, there is -- I'm sure you're aware, the Female Pelvic Medicine and Reconstructive Surgery board, which I did sit for, based on my experience, and passed, which is basically the same thing as urogynecology, minus the hysterectomy. I do not do hysterectomies but I do everything else that a urogynecologist would do.
Q. Okay.
A. A urogynecologist does a four-year obstetrics and gynecology residency so they only have approximately two years of surgical training and then they have a fellowship of three years, and it's centered around the pelvic floor.
But in my training, I worked with Drs. Rodney Appell and Timothy Boone, who are very renowned female urologists, and I did

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not feel the need to do a fellowship because I had excellent training with them.
Q. And you're talking about specifically a fellowship in urogynecology?
A. Or we call it a female urology fellowship from coming out of urology.
Q. Female urology, okay.
And you felt that the training that you had received during your residency qualified you to do -- to focus your attention on female urology issues without going through that fellowship?
A. Yes.
Q. How long have you treated women with stress urinary incontinence?
A. Including residency, 16 years.
Q. When did you start using polypropylene slings to treat women with stress urinary incontinence?
A. I was trained on it in residency, 2001, and then I used it in private practice starting in 2002 when I first began as a practitioner.
Q. Okay. And in 2002, the only

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polypropylene sling kits that were on the market were implanted using the retropubic method. Is that right?
A. That's correct.
Q. So you were trained in your residency to implant a retropubic sling?
A. Yes.
Q. And when you started in private practice, you continued to implant the retropubic sling. Is that right?
A. That's right.
Q. What brand did you use?
A. I'm sorry, what?
Q. What brand?
A. The Ethicon.
Q. Have you ever implanted anything besides Ethicon?
A. Yes.
Q. Which ones have you used?
A. AMS, Caldera, C-A-L-D-E-R-A, Boston Scientific. I think that's all.
Q. And at the time you started using these in your practice in 2002, did you believe that the retropubic was an effective

way to treat women with stress urinary incontinence?
A. Yes, very effective and very safe and much less invasive than what we had been doing for incontinence.
Q. Okay. Let's talk about that a little bit, going back to 2002. When you say that it was safe, did you rely on medical literature at the time to convince yourself that it was safe?
A. Absolutely. It was a big debate, you know, at residency, because -- and we were, you know, carefully looking at the literature at that time because it was a new procedure. Members of my faculty were skeptical, so we were, you know, looking at it carefully.
Q. Now, at the time that you started implanting these, the kits to treat stress urinary incontinence had been on the market for about four years. Is that right?
A. That sounds about right.
Q. Okay. And you know that there were no clinical trials done prior to the

launch of the TVT Classic. Isn't that right?
MR. SNELL: Form, misstates the evidence.
A. There were trials.
MR. SNELL: Foundation, too, for that one.
BY MS. KIRKPATRICK:
Q. Which ones did you rely on?
A. The ones in Europe that were done with Ulmsten and...
Q. Okay. So the Ulmsten, so that was what you relied on for the safety?
A. Uh-huh.
Q. Anything else besides the Ulmsten studies?
A. Are you talking about what I relied on in 2000?
Q. I just want to know what it was that you had looked at to convince yourself that this was safe.
A. I can't remember. There was multiple studies that -- there was always something coming out in the Journal of Urology that we would look at, at journal

club.
Q. But the one that stands out to you was the Ulmsten study. Is that right?
A. Well, that was in response to your question that there were no studies prior to the launch.
Q. Okay. So in addition to the Ulmsten study, which obviously you do recall, what other studies do you remember looking at, if any?
A. I don't remember.
Q. Were any of the studies that you looked at at the time designed to look at the long-term safety of the product when implanted permanently in women?
A. Well, at that point I think they didn't have more than maybe four- or five-year data, so I can't recall.
Q. Okay. So we agree that the maximum amount of time that could have been looked at at that time is probably about four to five years?
A. Correct.
Q. Do you recall whether any of the

studies that you looked at, however, were designed to look at the issue of safety as opposed to efficacy?
A. I don't recall. But I would think that there were, because that was our big question, is this going to be safe to put in, polypropylene mesh in women, into their vaginal area; so that was definitely on the forefront of our minds. Baylor residency, top residency program, we were all really looking at that carefully, and the conclusion was that it was safe.
Q. But you don't recall any studies that were specifically designed to look at the issue of safety?
MR. SNELL: Form.
A. That was too long ago. I can't specifically say any specific studies.
BY MS. KIRKPATRICK:
Q. And you'll agree with me, even if those -- if those studies did exist, the maximum amount of time they would have been looking at was about four to five years?
A. Yes.

Q. Do you have any concerns with using the retropubic approach to implant a polypropylene sling?
A. I'm sorry, could you repeat that question?
Q. Did you have any concerns about the safety of using a retropubic device to treat stress urinary incontinence?
A. Well, it has to be done properly. I think it's been well established that if it is done properly and in an appropriate patient, that it is safe. The risk to benefit ratio is quite favorable for women.
Q. Okay. What do you mean by "done properly"?
A. Following surgical principles, following the recommended guidelines for use.
Q. And when you're talking about that, are you talking about the instructions for use that, for example, Ethicon will publish with the kits themselves?
A. That's part of it, but also just applying general surgical principles that we're taught in residency.

Q. Okay. Anything else that you mean by "if done properly"?
A. Well, I mean, for me, I think there needs to be that just basic surgical attention to detail, meticulous handling of the tissues, and I think it's important to just be aware of each step that you're doing in a surgical procedure.
Q. Okay. Thank you.
And you also had said that in appropriate candidates.
A. Uh-huh.
Q. Who would not be an appropriate candidate for the implantation of a retropubic polypropylene midurethral sling?
A. Well, a patient that does not have healthy enough tissue, if their tissue is very thinned out, so there might be concerns about how they might heal.
Q. Uh-huh.
A. Or they do not have, of course, documented stress urinary incontinence, either by their history or by urodynamics; if they have only urge incontinence, of course

that wouldn't be appropriate.
Q. And of course it wouldn't be appropriate if they had neither stress urinary incontinence nor urge urinary incontinence, correct?
A. Yeah. Yeah, of course.
Q. So you need to have a diagnosis of the condition before it would be appropriate.
A. Yes.
Q. Okay. So apart from women who don't have SUI and women who may not have healthy tissue, is there any other contraindication that you believe exists for who would be an inappropriate candidate for a retropubic synthetic sling?
MR. SNELL: Form.
A. Not as a general category.
BY MS. KIRKPATRICK:
Q. Okay. How many retropubic devices have you implanted, approximately?
A. I think the number is around 300.
Q. About 300 total?
A. Yes.

Q. And of the 300 patients that you've implanted a retropubic device, can you give me a ballpark of how many you've had to remove or excise the device from? Do you remember?
A. It's going to be a very low number. I don't -- I mean, honestly, one or two that I would remove it.
Now, if there's a mesh exposure, if you're referring to that category as well, that's probably about a half a percent rate for my patients.
Q. So half a --
A. So 1 out of 200.
Q. So 1 out of 2- -- so you think that you've got probably one to two patients that you've actually had to go in and remove the sling and you've probably got one or two other patients that you've had to go and excise the mesh if there's an erosion. Is that correct?
A. Partially, yes.
Q. Okay. Why did you have to remove the mesh in the one or two patients? Do you

remember what the complications were?
A. I can't remember the details.
Q. Do you have a general memory?
A. No.
Q. What are the circumstances in which you, as a physician and as a surgeon, would choose to remove a retropubic polypropylene sling from a patient?
A. If they're having significant voiding dysfunction and obstruction and the sling really isn't effective, then I might go in and remove the part of the sling that's around the urethra, so a urethrolysis.
Or if they have a mesh exposure that can't be managed just with a small revision, then I might need to go ahead and take out the sling that's around the urethra and in the vagina.
Q. Okay. Anything else?
A. No.
Q. Okay. Now, at some point you began to use a transobturator sling as opposed to a retropubic, correct?
A. Yes.

Q. And if I remember correctly, is that about 2006?
A. Yes. Maybe -- I think it was before that.
Q. Before that?
A. Yeah.
Q. When did you start to do that?
A. I think it was 2004.
Q. 2004, okay. And what was the first transobturator midurethral polypropylene sling that you used?
A. The TVT-O.
Q. And you agree with me that the TVT Classic and the TVT-O are made with the same material, correct?
A. That's correct.
Q. But they're inserted into women differently, correct?
A. Correct.
Q. And they go through different parts of their anatomy in the insertion process?
MR. SNELL: Form.
A. The trocar does go through a

different area.
BY MS. KIRKPATRICK:
Q. And the mesh actually sits in a different part of the pelvic cavity. Isn't that right?
A. That's correct.
Q. Okay. Before you started implanting TVT-O slings, had you performed any surgery in the transobturator space in a woman?
A. No.
Q. Is there any other surgery that you perform as a urologist that occurs in the transobturator space of a woman?
A. No.
Q. Why did you change from using a retropubic to using a transobturator approach?
MR. SNELL: Form.
A. The TVT Classic had more of a risk of bladder perforation compared to TVT-O and it took longer to do.
BY MS. KIRKPATRICK:
Q. How long did it take to do the

TVT Classic?
A. About 20 minutes.
Q. And how long does it take to do the TVT-O?
A. About 10 minutes.
Q. So about a 10-minute -- okay.
What information did you rely on in making a decision to use the new surgical technique of implanting a polypropylene midurethral sling through the transobturator space?
A. I looked at the literature that was available at that time, and I can't remember specifically what it was. I apologize. But to show that it was as effective, because that was my concern, that it was going to be as effective as the TVT. It's faster, less risk of bladder perforation, but is it going to work as well.
Q. Okay. And you looked at the medical literature at the time and satisfied yourself that it was going to be equally effective?
A. Yes.

Q. What, if anything, did you do to examine or consider what complications may arise from the use of a midurethral sling through the transobturator approach as opposed to the retropubic approach?

A. Well, the initial literature that was available that would report the complications that they experienced. Also talking to other pelvic floor surgeons that had used it.

Q. Okay. And you'll agree with me as well that as far as long-term complications associated with use of a transobturator midurethral polypropylene sling that there was relatively limited data available at the time in 2004, correct?

A. That's correct.

Q. So you would have looked at both the efficacy and you would have looked at what you considered to be the short-term complications that may arise that would have been reflected in medical literature.

A. That's correct.

Q. Did you talk to anyone at Ethicon

about it?

A. Yes.

Q. Okay. Who did you talk to?

A. The sales rep.

Q. Uh-huh. Anyone else?

A. No.

Q. Did Ethicon provide you with any information that informed or helped you make a decision to start using the transobturator approach?

A. No.

Q. How did you get trained to do it?

A. My partner, Dr. Anhalt, he went to a course and then he came back and trained me.

Q. Talking about the literature that's out there, you agree with me that there's different types of studies that can be done to look at both issues of safety and efficacy in medical devices, correct?

A. Correct. You can do a prospective study, a randomized study, a retrospective study; so there's several different ways that you can look at it.

Q. So you can do a prospective study, a retrospective study, randomized --

A. Randomized controlled trial, you can just look at a cohort of patients.

Q. You could look at also, I guess, individual case reports.

MR. SNELL: Form.

A. Correct.

BY MS. KIRKPATRICK:

Q. What do you think are the best type of studies that can be done to establish the safety of a medical device?

A. Well, a randomized controlled trial is considered the top tier of medical evidence, but it's the hardest study to do.

Q. And when you say it's the hardest study to do, what do you mean?

A. It's hard, especially for surgical studies, to have patients trust in the roll of the dice as far as what procedure they're going to have ahead of time, because they don't know exactly what they're getting into ahead of time.

So there have been studies that

have not worked out, not specifically related to slings, but in surgery in general, where they couldn't accrue patients.

Q. Okay. And you would agree with me that's because in randomized controlled studies, most patients want to have a say in what kind of medical/surgical intervention they're going to have, correct?

A. They want to know what they're getting into, yes.

Q. And they want to know what the potential complications or potential side effects are from a certain procedure. Is that right?

A. Correct.

Q. And they want to know what the potential efficacy of the procedure is, correct?

A. Correct. But part of that's why you're doing the study, so yeah.

Q. Yeah. And those patients also, I'll put it in my everyday speak and the non-medical speak, but they kind of want to have some assurance that they're not going to

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end up worse off than they were when they went into this trial. Isn't that right?
MR. SNELL: Form.
A. I think everybody wants that when they go into surgery, yes.
BY MS. KIRKPATRICK:
Q. And they want to have some kind of feeling that they're not a human guinea pig in some kind of big surgical experiment. Isn't that right?
MR. SNELL: Objection.
A. Yes.
BY MS. KIRKPATRICK:
Q. And so that information is all particularly important to people in making a decision about whether to have a surgical procedure, which is, as you say, one of the limitations of an RCT, correct?
A. Correct.
Q. What would be the next tier down from an RCT?
A. The next tier down would be a prospective study where you're evaluating the results as they come in.

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Q. And so those are studies in which the device has already been implanted. Is that right?
A. Typically, yes.
Q. And now you're monitoring a series of patients to see what happens after you put the device in.
A. Correct.
Q. Okay. And then what is next after that?
A. And then a retrospective study.
Q. Okay. And can you describe what that is?
A. That's looking back at your data that you have collected.
Q. Okay. So it's like a data analysis, correct?
A. Correct.
Q. And you'd run like a statistical modeling to see what trends you can discern from the pool of data that you already have in your possession.
A. It can include that, it can include questionnaires of patients, calling

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patients, even examining patients, having them come back in a few years later and looking at where they are right now.
Q. Okay. And you will agree with me that when you're talking about a permanent medical implant, it's important to look at long-term clinical effects, correct?
A. I think, you know, when you can, obviously, yes. However, you know, you can't necessarily hold a device for 10 years while you're waiting for long-term studies.
Q. Okay.
A. If you see initial results that demonstrate safety and efficacy, then if the -- you know, if the benefit outweighs the risk, then you proceed forward and then you continue to follow and collect data, which is what I think we've seen with the TVT and the TVT-O, that over, you know, all these years that we've seen thousands of studies that show that or that bear out the safety that was initially seen when it was first beginning to be implanted.
Q. Okay. So I want to talk a little

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bit about risk-benefit because you just brought this up.
A. Uh-huh.
Q. There's risk-benefit as it applies in the medical literature, which would be what you're discussing, correct? Does the benefit of this product outweigh the risk. That's a different analysis than what an individual patient goes through to make a decision in her particular case whether the benefit outweighs the risk, correct?
MR. SNELL: Form.
A. Well, to some degree, yes, because each patient is individual. Each patient has different goals and different -- their health is at a different point, different ages, so as far as the literature, we have to look at the whole picture, the whole body of evidence to make a decision about different devices or drugs or what have you.
But, yeah, for each patient, it is. It's a discussion with her doctor and a decision about the risks versus the benefits.

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BY MS. KIRKPATRICK:
Q. Right. And so every patient is entitled to make her own decision about whether the potential risks are acceptable in her particular situation, correct?
A. Correct.
Q. And in order to make that determination, you'll agree with me that a patient has to be informed of all of the risks of a procedure, correct?
MR. SNELL: Form.
A. Well, it's impossible, really, to inform a patient of all the risks of each procedure.
BY MS. KIRKPATRICK:
Q. Okay. So how do you decide which risks you're going to tell your patients about and which ones you're not?
A. Well, for me, and I think for most physicians, you evaluate that patient and, you know, where they are and how they're going to respond to the therapy, tell them about any specific risks that they're at higher risk for or that would be more

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pertinent to their life, and also the main risks that are seen in this procedure or any procedure.
Q. Okay. And when you talk about main risks, there's two parts to that equation. The first is you look at just the statistical incidence of that risk over the population. Is that right?
A. Correct.
Q. But you also look at the severity of the potential complication, correct?
A. Correct. There's -- it's graded as far as a serious event or a minor event.
Q. Okay. So you could have a serious adverse event that happens in a very small, small percentage of the population, but it would be important to tell a woman that so she can make the decision whether the risk of that particular serious injury is relevant to her case and her decision, correct?
A. If there's a specific reason with that patient why you would tell her that, then yes. But for every patient, you don't

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need to tell them about every serious potential adverse event.
Q. Well, let me use an example for you. When you go in to do surgery, do you always warn your patients that there's a risk of death with surgery?
A. Personally, I do not.
Q. You do not?
A. But I know a lot of surgeons that do, yeah.
Q. Okay. How do you decide who gets the warning about the risk of death from surgery and who doesn't?
A. Well, I typically don't operate on patients with much of a risk of death. I mean, I can warn them of that when they're leaving my office, there's a risk of death when you drive home, because there's actually more risk of that than with the surgery that I do.
However, if there's a patient that's high-risk for kidney removal or if they just have a lot of major issues, then I would warn them of the risk of death.

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But from the surgeries that I do, the risk of death is so small that -- I mean, and also it's kind of obvious if you're going to surgery, you know, that some strange event could happen and you could die.
Q. Nobody likes to think of that, but you're right.
So what I'm trying to understand here is -- and maybe let me ask it like this.
A. Okay.
Q. When you have a patient who comes in to get a TVT-O implanted, are there certain patients that you warn that there's a risk of chronic pain?
A. Yes.
Q. Okay. Who would those patients be?
A. Well, most all patients, but, you know, particularly if it's a younger patient, they tend to have, in my experience, and I don't know that this has been borne out in the literature, but older patients don't seem to have as much pain issues in their pelvic area. I don't think their nerves are as

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sensitive.
So definitely with younger patients and sexually active patients, I will warn them that that is a very small risk, but it is a risk.
Q. Okay. What do you consider to be a small risk?
A. Oh, like 1 in 500.
Q. Okay. And do you reach that statistic from -- or rely on any medical literature in reaching the statistic that approximately 1 in 500 women who are implanted with a TVT-O may experience chronic pain?
A. I think that the studies that look at chronic pain show that it is very -- I mean, it's hardly reported at all because it's so rare.
Q. Okay.
A. And in my experience, I don't think I've seen any patient that had that from a TVT-O.
Q. Okay. So you haven't personally treated physicians [sic]. Can you identify

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any particular studies that you have in mind that you're relying on to support your opinion that it's extremely rare to have chronic pain following the implantation of a TVT-O device?
A. I could look through the studies. I don't have them at my fingertips, but I could look through them.
Q. Would glancing through what you have in your report help, or -- I don't want to send you on an exercise of reading 500 articles, but if there's anything that jumps out at you, I just would like to know what those are.
A. Uh-huh.
(Witness reviews document(s).)
A. Well, specifically for dyspareunia, dyspareunia, even in the short-term, was rare in the Schimpf study.
BY MS. KIRKPATRICK:
Q. Can you spell that for the court reporter?
A. Yes, S-C-H-I-M-P-F.
Q. Would that be what we've

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identified as Exhibit 4? Is that what you're referring to?
A. Yes.
Q. Okay, great.
(Witness reviews document(s).)
A. I can't remember the others right now. I'd have to go through -- go through my binders.
Okay, here's one. Athanasiou, A-T-H-A-N-A-S-I-O-U, he said no -- they said no patient reported persistent groin pain at the long-term follow-up.
And really, looking at the literature, there's really no mention of dyspareunia, groin pain. As far as, you know, persistent vaginal or pelvic pain, there's really not a lot of that. I mean, it's hardly mentioned at all in the literature.
BY MS. KIRKPATRICK:
Q. Okay.
A. And not -- you know, not really seen in practice.
Q. In your practice?

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A. Uh-huh.
Q. Okay. Let's go back to the discussion of just some general principles about the literature.
What does primary endpoint mean in the literature and designing a trial?
A. So the primary endpoint is when the study is designed, they're looking at the first thing that they want to evaluate. So, for instance, the subjective cure rate of stress urinary incontinence at one year would be the primary endpoint.
And then secondary would be the other side effects, the other complications that were observed in the study.
Q. So am I correct -- oh, do you need to grab that?
A. No, it's okay.
Q. So what happens when one is conducting one of these trials, there's a primary purpose, for example, to establish the efficacy of a particular device, correct?
A. Correct.
Q. And while doing that study,

there's other information that you may gather along the way that are relevant to other considerations, correct?
A. Correct.
Q. But the trial is designed with that primary endpoint in mind, correct?
A. Correct.
Q. Do you -- are you aware of any of the trials that you have -- or, excuse me, any of the literature that you relied on that have a primary endpoint of safety as opposed to efficacy?
A. Yes. Where is that...
(Witness reviews document(s).)
A. Okay, here's one of them. The Collinet, C-O-L-L-I-N-E-T.
Did you say specifically for the TVT-O or TVT?
Q. Well, let's establish that. We've agreed with me that the TVT-O approach differs from the retropubic approach, correct?
A. Yes.
Q. And so because they're different

surgeries, they have different types of complications associated with them, correct?
MR. SNELL: Form.
A. A couple of the complications are -- one of the complications is different.
BY MS. KIRKPATRICK:
Q. Okay. So in order to determine what the complications associated with the transobturator approach, we'd need to be looking at either TVT-O or transobturator studies, correct?
MR. SNELL: Form again.
A. Correct.
BY MS. KIRKPATRICK:
Q. Okay. So do you see anything in there related specifically to transobturator that was designed with the end purpose of measuring the safety of a transobturator midurethral sling?
A. Okay.
(Witness reviews document(s).)
A. Here's one that compares TOT to TVT, Ross. They were mainly looking at safety.

BY MS. KIRKPATRICK:
Q. And that was a primary endpoint of safety?
A. Yes, comparing the two procedures. That was one of the primary endpoints. Oh, and Seratti, that's the one I've been looking for. "Efficacy, adverse effects and prognostic factors at 5-year follow-up," Seratti, S-E-R-A-T-T-I.
(Witness reviews document(s).)
A. Those are the ones that I can find at this moment that kind of focus on safety, but I think there's more.
BY MS. KIRKPATRICK:
Q. Okay. Well, you know, it's not meant to be a memory test.
A. Okay, thank you.
Q. Let me just ask you just a couple of questions. Now, that Collinet that you cited, that's not an RCT, is it? It's actually a registry.
A. That's correct. It's a French registry, uh-huh.
Q. Okay. And so that's one of the

retrospective studies that we had talked about, kind of the third tier down on the --
A. I'd have to look at it to -- but just looking at the title, I think so.
Q. Okay. And do you recall that what they found in that article was that 2.7% of the women in that registry had residual pain following implantation?
MR. SNELL: Form.
A. I'd have to see the article. I can't recall.
BY MS. KIRKPATRICK:
Q. Well, you'd agree with me that 2.7 is significantly higher than the 1-in-500 number that you've cited from your experience?
A. Pain where, pain for how long? What are they talking about?
Q. Okay. Well, why don't we -- we can pull that out and look through that at lunch.
And the Ross article that you looked at, that was an RCT, correct?
A. Yes.

Q. Okay. And do you recall that that article reported that there was 15% groin pain at 12 months in the population studied there?
A. I don't recall. I'd have to see it.
Q. Okay. And then you also have given me, from before, the Exhibit 5, which is the Dr. Teo article about the "Randomized trial of tension-free vaginal tape and tension-free vaginal tape-obturator," do you remember that?
A. Yes.
Q. And that was a randomized controlled trial, correct?
A. Yes.
Q. And do you recall that 26.4% of the women in that study complained of leg pain after receiving the TVT-O?
MR. SNELL: Form.
A. Yes.
BY MS. KIRKPATRICK:
Q. And in fact, that the study was stopped because that was such a high

incidence rate of pain following the TVT-O procedure?
MR. SNELL: Form.
A. I think it was short --
BY MS. KIRKPATRICK:
Q. Shortened?
A. Short duration of pain. I don't think it was long-term pain at all. I'm not sure -- really sure why they stopped that study because it wasn't a severe effect.
Q. Okay. But of the studies that you could identify for me, none of them are long-term randomized control studies designed specifically to look at the incidence of chronic pain, are they?
A. I'd have to review them to be able to make a comment on that.
Q. Okay. And do you know whether any of them are long-term RCTs designed to look at the rate of dyspareunia following implantation of a transobturator midurethral sling?
A. I'd have to review them.
Q. Okay. And do you know whether

any of them are long-term RCT's designed to look at the rate of groin pain after the implantation of a transobturator midurethral sling?
A. I'd have to review the studies.
Q. And I don't want to go through all of them. Sitting here today, you just don't recall one way or the other whether they're long-term studies, whether they're RCTs versus registries and what the primary endpoint of those studies are; is that fair and accurate?
A. I've looked at so many studies, I'd have to really have them in front of me to be able to make an educated comment on it.
Q. Okay. I don't want to give you a memory test so I'm not going to ask you 10 questions to have you say, "I'm not sure."
A. Thank you.
Q. Let's talk about what you are opining about in this case. You're not -- you don't offer an opinion here that a woman cannot have chronic long-term pain as a result of an Ethicon TVT-O mesh implant, are

you?
A. No, I'm not.
Q. And you're not here to opine that a woman cannot suffer from de novo dyspareunia as a result of an Ethicon TVT-O device, are you?
MR. SNELL: Form. Go ahead.
A. That's correct, but it's very rare.
BY MS. KIRKPATRICK:
Q. Okay. But you will agree with me that a TVT-O -- an Ethicon TVT-O device to treat SUI can cause complications in some women, correct?
A. Correct.
Q. And you'll agree with me that the TVT-O device can cause groin pain?
A. Correct.
Q. And can cause chronic pain?
A. It can, yes.
Q. And it can cause acute pain?
A. Yes, as every surgery does.
Q. And can cause dyspareunia?
A. Yes, it can.

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Q. And it can cause vaginal pain?
A. I don't really see vaginal pain from it.
Q. You don't see --
A. No.
Q. And you don't think that it can cause vaginal pain?
A. I suppose it could.
Q. Okay. And you're not -- in looking at Ms. Huskey's medical records and in Ms. Huskey's IME and the pelvic exam you did of her, you're not testifying that she is not experiencing pelvic pain, correct?
A. That's correct.
Q. And in fact, the clinical observations that you have made are similar to the clinical observations noted by Dr. Blaivas in his IME, correct?
A. Correct.
Q. And they're similar to the clinical observations made by Dr. Steege in his IME, correct?
MR. SNELL: Form.
A. I believe that we all found that

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she had tenderness specifically on the left levator muscle and some tenderness throughout the vagina.
BY MS. KIRKPATRICK:
Q. And so I guess what I'm getting at is, your clinical observations aren't that different from the clinical observations that you read in the reports that were issued by the plaintiff's experts in this case, correct?
A. Correct.
Q. So where you differ is what the cause of those injuries are.
A. That's right.
MS. KIRKPATRICK: All right. If we could take a brief break, because I'd like to use the ladies' room, and then I'd like to look at your report and your IME related to Ms. Huskey.
THE WITNESS: Sounds good.
(Recess, 11:52 a.m. to 12:10 p.m.)
BY MS. KIRKPATRICK:
Q. Instead of starting with Ms. Huskey and then breaking and getting back

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into it, I'm going to actually ask you just a couple of other general questions, hopefully wrap those up again before lunch.
A. Okay.
Q. You will agree with me that a medical device manufacturer has a responsibility to make a safe product, don't you?
MR. SNELL: Form.
A. Well, they have the responsibility to make a product where the benefit outweighs the risks for patients.
BY MS. KIRKPATRICK:
Q. Would that be a 51 to 49 percent, or what do you mean by "outweigh"?
A. I mean, they can't put a number on it, but you have to have good results and you have to have -- there's always going to be a risk with any surgery, and you could say that it's not safe for any surgery because that patient had a complication.
So you have to look at the general -- the overall picture of the risks and the number of risks that you see based

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on -- compared to the efficacy of the product.
Q. Okay. Well, let's talk a little bit about the surgical risks. Now, there is a risk, I agree, associated with any surgery. Correct?
A. Yes.
Q. But there's a different set of risks that exists when a medical device is permanently implanted in a human body, correct?
MR. SNELL: Form.
A. Each surgery has its own individualized risk, whether it's a medical device or any kind of surgery. They have their own individual risks.
BY MS. KIRKPATRICK:
Q. Well, let me see if I can make this a little clearer to see if we're on the same page here. For a woman who's undergoing TVT surgery, TVT-O surgery, there is the risks, for example, of being under general anesthesia that come with any surgery, correct?

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A. Correct.
Q. And there's the risks of making an incision on the vaginal wall that come with any type of pelvic surgeries that are done, correct?
A. That's done, yeah, with an abdominal wall incision.
Q. And anywhere that you make an incision in the body, you can get a localized infection at the area of the incision, correct?
A. Yes.
Q. And that's the same for TVT-O surgery as it is for hernia surgery as it is for open heart surgery, correct?
A. Correct.
Q. So what I'm getting at is, there's certain risks that are attendant to any surgery that you perform, correct?
A. Correct.
Q. And then separate and apart from that, there are risks that go along with specific individual surgeries, correct?
A. That's right.

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Q. And in the case of looking at a permanently implantable medical device, there's the risks of undergoing the actual surgery at the time of surgery, correct?
A. Yes.
Q. And then there's the risks that you may experience because you have a permanently implantable medical device in your body, correct?
MR. SNELL: Form.
A. Well, there may be unique risks to that procedure. For instance, with TVT and TVT-O, the risks are the same as any pelvic surgery with the exception of mesh exposure.
BY MS. KIRKPATRICK:
Q. Okay. So mesh exposure is a risk that is unique to the TVT-O or, in fact, any polypropylene sling, correct?
A. Correct.
Q. And it's actually any kind of permanently implantable mesh into the pelvic cavity, whether it's for SUI or pelvic organ prolapse, correct?

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A. Right.
Q. So that is a unique risk. And in addition to that, when you implant a foreign body like the mesh into the pelvic cavity, you incite a foreign body reaction, correct?
A. Well, even with just surgery, with sutures that are used to close the vaginal wall from any pelvic surgery, you get a foreign body reaction.
Q. How often do you use polypropylene permanent sutures in the pelvic cavity?
A. Well, if I do a pubovaginal sling, I would use it for that, on the ends of the sling.
Q. Okay. Anything else that you use a permanently implantable polypropylene suture in the pelvic cavity?
A. Well, me personally, no. I use the polypropylene mesh for the sacrocolpopexy with permanent Ethibond sutures to attach that to the vaginal wall. I know that some pelvic surgeons will do a sacrospinous ligament fixation with polypropylene sutures,

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and those can erode.
Q. And do you know of any surgery that leaves polypropylene sutures in the vagina?
A. Any surgery at all?
Q. Uh-huh.
A. Well, sacrospinous ligament fixation, pubovaginal sling.
Q. I mean in the vaginal wall itself.
A. Oh, in the --
Q. In the vagina, yeah, as opposed to the -- I'd asked you before about the pelvic cavity. Now I want to move on to are you aware of any surgery that is performed that would leave permanently implantable polypropylene sutures in a vagina?
MR. SNELL: Form.
A. I don't know.
MR. SNELL: Do you mean inside the vagina or in the wall of the vagina, in the rectovaginal space behind it? What do you mean by --
A. No, not in the wall of the

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vagina.
BY MS. KIRKPATRICK:
Q. And in fact, absorbable sutures are generally used, if necessary, to close up the vaginal wall, correct?
A. Correct.
Q. And in fact, absorbable sutures are used in the majority of surgeries or repairs that require surgery throughout the human body, correct?
MR. SNELL: Form.
A. No.
BY MS. KIRKPATRICK:
Q. No, you don't agree with that?
A. No.
Q. Okay.
A. Depends on the surgery that you're talking about. I mean, heart surgery they use polypropylene, cardiac surgery and vessels, they don't use absorbable sutures.
Q. Okay. But you would agree with me that surgeons and physicians would default and use an absorbable suture in the first instance, and if that was not strong enough

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or was not for the particular application or not appropriate for that particular patient, they would then go to a polypropylene permanently implantable suture, correct?
MR. SNELL: Form, foundation.
A. I mean, that's a broad question. I can't -- I mean, that's a very broad question. I need more specific insight into what you're asking.
BY MS. KIRKPATRICK:
Q. Okay. Well, you know, I don't want to get too far afield on this. But with a pubovaginal sling, that's when you use a patient's own tissue to perform a repair for SUI, correct?
A. That's correct.
Q. And in that case, you do use permanent implantable polypropylene sutures, correct?
A. That's correct.
Q. And the actual sling itself cannot and does not erode in that surgery, correct?
A. It can.

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Q. You've seen a woman's native tissue erode in a pubovaginal sling into an adjacent organ?
A. It's been reported, yes.
Q. Okay. Where has that been reported?
A. I'd have to go through the papers, but there's --
Q. Would it be in the materials that you've provided to me?
A. Yes.
Q. If that has been reported in the medical literature, you would have noted that here?
A. Yes.
Q. And it's the actual sling material itself as opposed to the polypropylene sutures that you believe can erode into an adjacent organ?
A. It can, yes.
Q. Have you ever seen it?
A. I've never seen it, no.
Q. Okay. Have you ever used polypropylene slings in the bladder --

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MR. SNELL: Form.
BY MS. KIRKPATRICK:
Q. -- for any kind of bladder surgery? I'm sorry, suture, polypropylene suture in the bladder.
A. Okay.
MR. SNELL: Form.
BY MS. KIRKPATRICK:
Q. No wonder you were looking at me like I was crazy.
A. Yeah.
Q. I was curious, where is she getting that?
A. No.
Q. Okay. Why not?
A. We use absorbable suture in that. Absorbable suture is adequate for that application.
Q. Okay. And actually, using the absorbable suture in the bladder application, it eliminates the risk of potential erosion, correct?
A. Decreases the risk.
Q. Have you ever seen an absorbable

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suture erode?
A. No, I have not.
Q. Have you ever seen that reported in the medical literature?
A. I don't think so.
Q. Okay. What I'm getting at is in these applications, it's the polypropylene suture that erodes as opposed to the absorbable suture or the native tissue.
MR. SNELL: Form.
A. Yeah. I mean, a permanent structure is going to have potentially more likelihood than an absorbable suture because it's there longer.
BY MS. KIRKPATRICK:
Q. And you'll agree with me that the amount of polypropylene used in a midurethral sling greatly exceeds the amount of polypropylene that's used in the sutures used to secure a pubovaginal sling, correct?
A. It is more polypropylene, yes.
Q. And it's a lot more polypropylene?
MR. SNELL: Form.

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A. Well, it's a 1-centimeter mesh tape that's used.
BY MS. KIRKPATRICK:
Q. Okay. And it's a 1-centimeter mesh tape that's made out of single-filament polypropylene, correct?
A. Correct.
Q. And the suture itself is just a single filament of polypropylene, right?
A. Correct.
Q. That's used to close up a small hole, correct?
A. Right.
Q. About how much polypropylene -- single filament of polypropylene do you use in a suture?
MR. SNELL: Form.
A. Can you restate that?
BY MS. KIRKPATRICK:
Q. How long is it? Is it a centimeter, 2 centimeters, 3 centimeters, 4?
MR. SNELL: Form.
A. What application are you talking

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about?
BY MS. KIRKPATRICK:
Q. In a pubovaginal sling.
A. Pubovaginal sling, it would be about 10 centimeters.
Q. So you use 10 centimeters total of a single-filament --
A. 10 centimeters on each side.
Q. Okay. So 20 centimeters, thank you, so that's total.
Okay. So we had talked a little bit before about your experience in removing retropubic slings. Do you remember that?
A. Yes.
Q. And you told me that you had removed about 300 -- I'm sorry. You had implanted about 300 total and you had removed 1 to 2 and you had, just on a repair, of about 1 to 2. Is that right?
A. Correct.
Q. I forgot to ask you how many transobturator slings you've implanted.
A. About 700.
Q. And do you still use the Ethicon

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TVT-O?
A. Yes.
Q. And how many TVT-O's have you removed?
A. One.
Q. And how many have you --
A. It's very unusual.
Q. -- gone in to do a revision on?
A. For mesh exposure, for obstruction? What are you referring to?
Q. You were the one who made the distinction that there was a difference between doing a removal surgery and then doing what you consider to be a less invasive revision surgery. So you've done one of the more invasive removal surgeries and I'm trying to figure out how many of the less invasive revision surgeries you have done.
A. I don't have a number at the top of my head, but it's, you know, maybe out of 700, there may be 20 that I had to go in and cut the sling or go back for a mesh exposure somewhere, ballpark that number, and that would include my patients and patients that

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were referred to me.
Q. Okay. And you would agree with me, though, with the transobturator slings, you can't completely remove it if something goes wrong. Is that right?
A. It can be completely removed.
Q. You think you can remove it without damaging a woman's pelvic anatomy?
A. Well, you have to dissect through the muscles and it's very difficult and it's very rarely done, but it can be completely removed. And damaging -- I mean, it depends on how you define that. You -- you know, you do have to go through muscle, so we don't do it very often. It's kind of painful to recover from.
Q. What muscles do you have to go through in a removal surgery?
A. It's the muscles of the obturator foramen.
Q. Anything else?
A. No.
Q. Okay. And you know that Ms. Huskey had to have her sling partially

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removed. Is that right?
A. It was partially removed, yes.
Q. Okay. And when it was partially removed, you are aware that her physician reported that some of the sling retracted back behind the pubic bone. Is that right?
MR. SNELL: Form.
Go ahead.
A. Well, he was pulling on it to try to dissect it as far as he could, so he was putting tension on it whenever he cut it, so I would expect it to retract, just like any tissue would.
BY MS. KIRKPATRICK:
Q. Okay. But at least you'll agree with me it's certainly not easy to fully remove a transobturator sling if a complication arises, correct?
A. That's correct.
Q. We had also started to talk about some of the warnings that you gave to your own patients who receive the TVT-O, and I had asked you about what warnings you particularly tell your patients of potential

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complications.
Can you give me the kind of laundry list of complications that you would routinely tell all of your patients are potential complications from a TVT-O?
A. Well, in --
Q. And when I say TVT-O, I mean any transobturator midurethral polypropylene sling.
A. So in general, I will tell them about the risk of bleeding, infection, injury to the bladder or the urethra, groin pain, which is typically transitory, failure of the wound to heal with mesh exposure and need for further surgery to repair that, pain, chronic pain, dyspareunia, de novo urge incontinence, persistent urge incontinence, urinary retention, temporary or permanent, requiring sling release, potential sling removal.
Q. And for each of those, you think that is important information to provide to a woman so she can make an informed decision as to whether she's willing to accept the risks of the implantation of a TVT-O sling,

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correct?
A. Most women, yes. And some are more important to some women than to others.
Q. Okay. Are there any of these that you think are particularly important to thin, active women?
MR. SNELL: Form.
A. I think they're all important to thin, active women.
BY MS. KIRKPATRICK:
Q. Okay. Are there any other -- correct me if I'm wrong on this, but I think you also said that there are sometimes warnings that you give patients that might be unique to their particular circumstances or medical conditions.
Are there any particular medical conditions or circumstances that you can think of that would warrant different additional warnings regarding the implantation of a TVT-O or a transobturator midurethral sling?
MR. SNELL: Form.
A. Well, if a patient is sexually

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active, then I would warn her about the risk of dyspareunia with any pelvic surgery. But if it's an older patient that's not sexually active, then it's not -- you know, it's not as important.

For a patient with mixed incontinence, with urge incontinence, I would focus on the risk of persistent urge incontinence.

For a patient with poor bladder emptying or a difficulty emptying her bladder, I would warn her of the risk of retention, which might be increased for that patient.

And if a patient has thin tissues, atrophy or radiation, we would have a discussion about that, about the risk of not being able to heal as well, or if she's a smoker, chronic smoker, we would have a discussion about that so that she could make an informed decision.

BY MS. KIRKPATRICK:

Q. Okay.

A. And I might start a patient with

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atrophy on estrogen ahead of time, if it's medically warranted.

Q. Okay. And atrophy is something that happens in a significant population of menopausal women, correct?

A. Yes.

Q. And you would expect to see some change in or thinning of their vaginal tissue with menopause, correct?

A. Yes.

Q. Do you tell all of -- and, you know, barring some godforsaken circumstance, most women hope that they make it until they're old enough to be in menopause, correct?

A. Yes.

Q. And you would just assume that most of your patients who are coming in are likely to get to the point of menopause if they're not already there, right?

A. Correct.

Q. Do you tell any of your patients about the risks that may be attendant to menopausal changes in their vaginal structure

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and the implantation of a TVT-O device?

A. I don't think that's really been borne out in the long-term literature, the 17-year data going out on TVT with, you know, exposure suddenly occurring or erosions occurring.

So that's part of the discussion with the mesh exposure, a need for further surgery down the line, but I don't specifically talk about that because I don't think that's really been borne out in the vast experience that we have with TVT and TVT-O.

Q. Okay. Now, just talking about pain just for a couple of minutes, there's different kinds of pain that anyone can experience, correct?

A. Correct.

Q. And I'd like to use the example, you can have the regular headache that you've got to take a couple of Advil for, right, and that's different from the pain you experience with a migraine, correct?

A. Correct.

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Q. Or the pain that you might experience with a concussion, correct?

A. Yes.

Q. Even though they all fall under the kind of umbrella of being a headache.

A. Correct.

Q. And that also is borne out with pelvic pain, correct?

A. Yes.

Q. And there's different kinds of pelvic pain that women can experience?

A. Yes, there's all kinds of different types of pelvic pain.

Q. And there's pelvic pain, for example, that women can experience with menstrual cramps?

A. Yes.

Q. And there's pelvic pain that you can experience if you have a vaginal infection or a yeast infection or something like that?

A. Right.

Q. And there's pelvic pain that you can have from having a bladder infection or

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something like that, correct?
A. (Witness nods head.)
Q. And do you find in your practice that many women are able to, for example, distinguish between the pain of a bladder infection and menstrual cramps, for example?
A. Yes.
Q. And women generally can differentiate between the degree of pain that they're experiencing pelvically?
MR. SNELL: Form.
Go ahead.
A. Most of the time, but there is a lot of overlap in the pelvic area so sometimes it's very difficult to pinpoint where the pain is coming from.
BY MS. KIRKPATRICK:
Q. Okay. And the same is also true that there's different types of dyspareunia and pain with sex, correct?
A. Yes.
Q. And so there's dyspareunia that can be caused by vaginal dryness that's brought on by menopause, correct?

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A. Yes.
Q. And that's different than the dyspareunia or painful sex that someone can have following, for example, a hysterectomy, when there's some kind of scarring at the vaginal apex, correct?
A. Yes.
Q. And all of that's different from the type of dyspareunia that you would experience if you have a point of tenderness on your vaginal wall in some way, correct?
MR. SNELL: Form.
A. Probably, yes.
BY MS. KIRKPATRICK:
Q. Okay. So dyspareunia isn't dyspareunia isn't dyspareunia, correct?
A. Right.
Q. And you feel that it's important to look at each patient individually to look at their specific symptoms and their specific circumstances to distinguish what type of pelvic pain they're having, correct?
A. Ideally, yes.
Q. Or what type of dyspareunia

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they're experiencing, correct?
A. Yes.
Q. Okay. And infection is the same; there can be an acute infection at a surgical site, correct?
A. Yes.
Q. And that's resolved in one particular way, correct?
A. Yes.
Q. And then there can also be chronic infections, correct, and those differ from the acute infection?
A. Yes, sometimes.
Q. Okay. And they're treated differently --
MR. SNELL: Form.
BY MS. KIRKPATRICK:
Q. -- than an acute infection?
A. Usually still treated with antibiotics, if it's a bacterial infection, yes.
Q. But it may be the difference between applying, for example, an antibiotic ointment to the site of a surgical incision

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on your skin versus oral antibiotics versus IV antibiotics, correct?
MR. SNELL: Form.
A. It's hard to just categorize it that acute you do this and chronic you do this, because it's --
BY MS. KIRKPATRICK:
Q. Okay. Fair enough. Fair enough. But you'll agree with me that those are different types of infections and they can't all be lumped together, because they have to be examined and treated differently as to what their particular source is and what the particular duration is, correct?
MR. SNELL: Form.
Go ahead.
A. Yeah, you have to take the patient's current situation into consideration, what kind of organism you have, the patient's symptoms, how sick they are; that all has to be taken into consideration.
BY MS. KIRKPATRICK:

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Q. Okay. And there's also subclinical infections that can exist in the body as well, correct?
A. Yes.
Q. Okay. Now, you've testified earlier that it takes about 10 minutes to do a TVT-O surgery. Is that right?
A. Correct.
Q. And how long is it for a woman from the time she is, you know, wheeled into the operating room till when she comes out of anesthesia?
MR. SNELL: Form.
A. Till she comes out of the operating room or wakes up in recovery room?
BY MS. KIRKPATRICK:
Q. Wakes up in the recovery room.
A. So --
MR. SNELL: Hold on. Same objection.
Go ahead.
A. Probably about an hour and a half, hour and 45 minutes.
BY MS. KIRKPATRICK:

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Q. Okay. So she's under general anesthesia for about one hour and 45 minutes with a TVT-O procedure?
A. No, she's under a general anesthetic about 20 or 30 minutes.
Q. Okay, 20 to 30 minutes, okay, you're right. So it's about an hour and 45 minutes from start until when she wakes up and about 30 -- 20 to 30 minutes of that she's under general anesthesia?
A. Correct, and the rest she would be in the recovery room just kind of coming out, you know, breathing on her own, not being administered more anesthesia.
Q. Okay. How long does it take you to perform a pubovaginal sling surgery?
A. 45 minutes.
Q. So it's a difference of about 35 minutes of actual surgery time?
A. Uh-huh.
Q. How long is it from the start when she's wheeled into the operating room till a woman comes out of anesthesia with a pubovaginal sling?

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A. The prep takes a little longer, so it's probably about two and a half hours.
Q. Okay. So we're tacking an extra maybe 45 minutes on to the total time?
A. Yes.
Q. Okay. Now, removal surgeries. The surgery that you did to remove the TVT-O, how long did that take?
A. About 20, 30 minutes.
Q. Okay. And is that about the same amount of time under -- from the beginning to coming out of general anesthesia as the TVT-O procedure itself?
A. Yes.
Q. About an hour? You know from talking to your colleagues that some of their removal surgeries can be significantly longer than that, correct?
A. Yeah. I've read even in some of the records that they take longer to do it.
Q. Do you remember how long Ms. Huskey's took?
A. I don't remember.
Q. And you will agree with me that

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the removal surgeries can be significantly more complicated than the original implantation surgery for the TVT-O, right?
MR. SNELL: Form.
A. It can be harder to find the sling if it's not a dyed sling.
BY MS. KIRKPATRICK:
Q. And the removal surgery requires dissection of some of the pelvic tissue, correct?
A. Well, it requires dissecting around the urethra, primarily.
Q. And that can cause additional scar tissue, correct, simply because you're having more surgery in the same location?
A. It could, yes.
Q. Are there any other complications that you think are risks that come from the removal surgery itself?
A. No.
Q. So just the possibility of additional scarring?
A. Yes.
Q. Okay. We've been talking a lot

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about kind of the procedure that's used here. You're not a biomaterials expert, correct?
A. Well, I know about the materials that I use for surgery, so I would say that I -- you know, I'm knowledgeable about what I implant in patients.
Q. Okay. What's the Ethicon TVT-O sling made of?
A. Polypropylene.
Q. Okay. What's added to that polypropylene?
A. What's added to it?
Q. Uh-huh.
A. I don't know if anything's added to it.
Q. Do you know if there's any antioxidants used in it?
A. No, I don't know.
Q. Do you know what its molecular weight is?
A. I've seen it before, but I don't know off the top of my head.
Q. Do you know whether it's been oxidized before it's been placed into a

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woman's body?
A. No.
Q. Do you know anything about the process of oxidation of polypropylene?
A. No.
Q. And that's not the type of information -- you know that it's made of polypropylene, but you're not intending to offer opinions here concerning the chemical processes that are involved with polypropylene, correct?
A. I don't know about the chemical processes.
Q. Okay. So you would defer -- you would defer to other experts who would be biomaterials experts or who would be specialists in polypropylene for that particular type of information?
MR. SNELL: Form.
A. I know how it -- I focus on it from the perspective of my patients.
BY MS. KIRKPATRICK:
Q. Okay. So you focus, though, on how you believe the polypropylene sling

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performs in your patients, both from an efficacy standpoint, correct, and from complications that you see?
A. From my experience and from the vast body of literature that's available on polypropylene slings.
Q. Okay. But I guess I'm just trying to figure out what the parameters of your testimony are. You're not going to come in and you're not planning on holding yourself out as an expert on polymers and polypropylene and degradation or any of those particular issues related to polypropylene, are you?
MR. SNELL: Form. And I will say she is. I am putting her up on that, and it is in her report.
BY MS. KIRKPATRICK:
Q. Okay. How does polypropylene degrade?
A. It doesn't degrade.
Q. So your opinion, sitting here today, that there is no way that any polypropylene that exists in this world can

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degrade?
MR. SNELL: That's overbroad, form.
Go ahead.
A. That's a very broad question. You know, from how it's used in the body in sutures and in slings, it doesn't degrade; that's why it's a permanent suture. That's why heart surgeons rely on it and cardiac surgeons rely on it to sew up your aorta when you have aortic surgery.
So if it degraded, it would not be used in that application. There's no clinical degradation that occurs.
BY MS. KIRKPATRICK:
Q. So you believe that there's no evidence that exists, either in Ethicon's own documents or in the literature, that supports the theory that polypropylene sutures can degrade --
MR. SNELL: Form.
Go ahead.
BY MS. KIRKPATRICK:
Q. -- in vivo?

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MR. SNELL: Form.
A. I mean, I can't say that there's nothing out there that they didn't do any kind of manipulation to polypropylene or look at it a certain way and found some degradation there, but does it matter to patients and to this case, no.
BY MS. KIRKPATRICK:
Q. Has Mr. Snell or any of the attorneys for Ethicon provided you with any Ethicon documents reflecting degradation of polypropylene sutures?
A. I mean, I think I saw some internal communication, I can't remember if it was from Mr. Kountze or from Mr. Snell, I don't remember, but I know that that is out there, that that was something that the engineers were talking about and Ethicon was talking about.
But clinically, I'm telling you it does not make a difference, and I don't believe that there's degradation that occurs that it makes any hill of beans' difference for patients.

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Q. Okay. So let me just figure out what you are testifying about and what you're not testifying about. You don't have a basis for saying whether polypropylene does or doesn't degrade.
What you are here to offer your opinion on is that regardless of whether polypropylene degrades or doesn't degrade, there's no clinical significance to a particular patient?
A. I don't think it degrades.
MR. SNELL: Hold on, hold on, hold on. Form. That misstates, too.
Go ahead.
A. I don't think it degrades and I think there's other evidence that shows that it doesn't degrade.
BY MS. KIRKPATRICK:
Q. Have you asked Ethicon, in reaching that opinion, to provide you with all of the information that they have concerning the potential degradation of polypropylene sutures?
A. No.

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Q. And don't you think that the information that Ethicon has and the knowledge that Ethicon has concerning the degradation of polypropylene sutures would be something that you would want to see in reaching your opinions concerning the degradation of polypropylene sutures?
MR. SNELL: Form.
A. No.
BY MS. KIRKPATRICK:
Q. You don't think it's important what your -- what Ethicon has said about its own sutures for you to reach your conclusion. Is that right?
A. Right.
Q. Okay. Have you ever tested it to see whether it degrades?
A. No.
Q. Have you ever looked at polypropylene under a microscope?
A. I've seen pictures of it under a microscope.
Q. Have you looked at it yourself?
A. No.

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Q. Have you ever looked at explanted polypropylene sutures and analyzed them to see whether there's any degradation in them?
A. No, I have not.
Q. Have you ever looked at explanted polypropylene mesh to see if there's any degradation in that mesh?
A. I've looked at -- when I've taken it out of patients, I've looked at it and it's intact.
Q. Okay. Let me just clarify. Have you ever looked at it microscopically to see whether it has degraded microscopically?
A. I've looked at the images that the pathologists have provided to me because I get images back from them.
Q. Okay. How many of those images have you looked at?
A. I don't know, 10, 20.
Q. Have you ever asked a pathologist to see whether the polypropylene had deteriorated?
A. No.
Q. That's not something that you

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standardly do when you remove polypropylene from a woman?
A. No, because it doesn't deteriorate.
Q. How do you know that?
MR. SNELL: Form, asked and answered.
A. Because it doesn't. It's a permanent suture. You can go back in 20 years and you'll still find it in there.
BY MS. KIRKPATRICK:
Q. And so your -- is it your opinion here that because 20 years from now, you can find a polypropylene suture where you implanted it and it has not completely disappeared, therefore it cannot degrade?
MR. SNELL: Form.
A. 20, 30, 40 years, it's going to be there. It's not degrading.
BY MS. KIRKPATRICK:
Q. Do you think it can crack?
A. No.
Q. Do you think that it can release particles from the surface?

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A. No.
Q. Do you think that it changes its chemical composition in any way at all?
A. No.
Q. Do you think that polypropylene used in the body can change its molecular weight?
A. No.
Q. Do you think that polypropylene that is used in the body can undergo any mechanical changes to it?
MR. SNELL: Form.
A. Depending on where it's placed and what happens with that patient, it could move slightly, because it's -- you know, just the position of it, like a hernia repair, if a patient gained a lot of weight, it could change its position slightly, if that's what you're referring to. But it doesn't just change on its own.
BY MS. KIRKPATRICK:
Q. Okay. And once again, the basis for your opinion on that is when you have looked at the polypropylene that you've

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removed, you don't visibly see deterioration?
MR. SNELL: Form.
A. That's part of it, but also because polypropylene is relied upon by surgeons throughout the world for the last 40 years as a permanent suture. If we were having aortas busting open after 30 years, we wouldn't be relying on it.
BY MS. KIRKPATRICK:
Q. So that's the basis for your opinion here, it's not any independent study that you've done, correct?
MR. SNELL: Form.
A. In looking at the literature as well. It's not reported as degrading.
BY MS. KIRKPATRICK:
Q. You've never seen any literature that reports polypropylene degrading?
A. Not any significant good literature. Some remote studies.
Q. Okay. What literature have you been provided with by Ethicon regarding degradation? What articles have you looked at?

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A. I can't recall right now.
Q. Okay. And when you say not any good literature, what literature are you referring to that would be -- I don't want to say bad literature just because it's the opposite of good -- that documents or deals with degradation of polypropylene in the body?
A. I mean, I think there was maybe a polymer article or something like that that was talking about it in some journal, but I can't recall. But nothing in the major body of literature that has brought that up as an issue. It's just not an issue.
Q. You don't believe that that's an issue at all?
A. No.
Q. And you don't believe that that's an issue that's been addressed in the medical and scientific literature?
A. No.
Q. And it's not an issue that was addressed in the materials that were provided to you by Ethicon, either from their internal

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documents or from the literature that they provided you with, correct?
MR. SNELL: Form.
A. Correct.
BY MS. KIRKPATRICK:
Q. Okay. And you haven't done any -- you don't have any specialized training in polymer chemistry, do you?
MR. SNELL: Form.
A. Well, I'm a chemical engineer, so I had some training in polymers and chemistry.
BY MS. KIRKPATRICK
Q. Okay.
A. But, you know -- and that was a long time ago. But, I mean, my main concern is with patients, you know, the materials that I put in patients and how they -- what the literature bears out and how they respond to it.
BY MS. KIRKPATRICK:
Q. So when you take a TVT-O or any kind of midurethral sling out of a patient, does it look exactly the same as it did when

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it went in?
A. Sometimes it does, yeah.
Q. Okay. And when -- how often is that?
A. Most of the time.
Q. Most of the time --
A. Yeah.
Q. -- you take out a soft, pliable, pristine --
A. It's this -- yeah, and it's the same strip but it has the ingrowth of tissue in it. But other than that, typically it's just laying, you know -- laying nice and flat. It does not look degraded or deformed or rolled or curled or twisted or anything.
Q. Would you feel differently if you learned or saw evidence that the resin used in Ethicon meshes have additives that weren't supposed to be used in the human body?
MR. SNELL: Form, foundation.
A. No, because it's been proven in millions of women that it's not a problem.
BY MS. KIRKPATRICK:
Q. So you wouldn't be interested in

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that information?
A. No.
Q. Okay. And if you learned that Ethicon meshes had additives that weren't supposed to be used in the human body, you don't think that that's something that a woman, in making a TVT -- a decision to have a TVT-O, would have the right to know?
MR. SNELL: Form, foundation.
A. No, I don't think it's -- I don't think it's pertinent.
BY MS. KIRKPATRICK:
Q. And you don't think it's pertinent and you don't think that a woman has the right to know that?
MR. SNELL: Same objection, form and foundation. Asked and answered.
A. Do you want me to answer that again?
BY MS. KIRKPATRICK:
Q. Please.
A. Okay. No, I don't think so.
Q. Okay. And there's nothing that you could learn or you would want to know

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about the specific material used in a TVT -- an Ethicon TVT or TVT-O product that would change your opinion, is there?
A. Can you repeat that question?
Q. Probably not. I'm going to reread it. I don't think I can do that.
There's nothing that you could learn or you would want to know about the specific material used in an Ethicon TVT or TVT-O product that would change your opinion on this topic, is there?
MR. SNELL: Form.
A. No.
BY MS. KIRKPATRICK:
Q. Okay. And there's nothing that you could see in the medical literature about degradation of polypropylene that would change your opinion on this matter?
A. No, because it's not going to outweigh all the other literature and all my experience.
Q. Okay. Why don't we take a break for lunch.
MR. SNELL: That sounds good.

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(Recess, 12:50 p.m. to 1:49 p.m.)
BY MS. KIRKPATRICK:
Q. Okay. I want to turn to the instructions for use.
A. Okay.
Q. And I believe we'll mark this as Exhibit 9.
(Whereupon, Exhibit Pramudji-9, Gynecare TVT Obturator System Instructions for Use, was marked for identification.)
BY MS. KIRKPATRICK:
Q. And you've seen that before, Dr. Pramudji, haven't you?
A. Yes.
Q. And this was actually something that the lawyers for Ethicon had given you in connection with your testimony. Is that right?
A. Yes.
MR. SNELL: Objection, form.
BY MS. KIRKPATRICK:
Q. I'd like you to look at the last two pages here.

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A. Okay.
Q. And you'll see under the warnings and precautions, it says not to use the TVT-O for patients who are in anticoagulation therapy. That doesn't apply to Ms. Huskey, does it?
A. Correct.
Q. And she didn't have a urinary tract infection at the time that you could see in the records, correct?
A. Correct.
Q. Was there anything else about Ms. Huskey that in your opinion made her not an appropriate candidate for the implantation of the TVT-O --
A. No.
Q. -- sling?
A. No.
Q. Okay. It also says here that "The Gynecare TVT Obturator procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks."

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And you will agree with me that not every woman's pelvis is identical to the next woman, correct?
A. Correct.
Q. And that the placement of nerves, particularly the peripheral branches of nerves, can differ from patient to patient, correct?
A. Correct.
Q. And even the placement of the vessels can be, you know, a little bit different from patient to patient, correct?
A. Correct.
Q. And there's a difference in how you do surgery on women who are obese, correct?
MR. SNELL: Form.
A. There may be slight adjustments that you would make, but it's generally the same.
BY MS. KIRKPATRICK:
Q. Okay. So you would take into account if a woman was obese --
A. Yes.

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Q. -- and that's different than things you may take into account if a woman is thin --
A. Correct.
Q. -- or of a normal weight?
A. Yes.
Q. Okay. Now, you'll see here it says, "Do not perform this procedure if you think the surgical site may be infected or contaminated." Do you see that here?
A. Yes.
Q. Okay. Now, the surgical site is in the vaginal wall, correct?
A. Yes.
Q. And the vagina, you'll agree with me, is a contaminated space?
A. It is. Clean -- we consider it clean-contaminated after the prep.
Q. Clean-contaminated, but it's still contaminated, correct?
A. Correct.
Q. And there's still bacteria, naturally occurring flora in the vagina, even after it's clean-contaminated and prepped for

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surgery, correct?
A. Yes.
Q. So can you explain this to me, how -- it sounds to me like Ethicon is recommending that you don't perform this procedure in any event because the surgical site is always contaminated.
Can you explain that to me?
MR. SNELL: Form and foundation on your understanding of Ethicon.
A. Well, I think that they mean grossly contaminated. If there is a gross infection or if there is some stool, you know, fistula, something where it's grossly contaminated, it would be contraindicated.
But it's, you know, obviously you would have a hard time doing any kind of vaginal surgery if you couldn't do it -- if you're broadly defining contaminated as including clean-contaminated.
BY MS. KIRKPATRICK:
Q. So you will agree with me maybe that's not precisely worded --
MR. SNELL: Form.

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BY MS. KIRKPATRICK:
Q. -- to reflect what you're describing, correct?
MR. SNELL: Form.
BY MS. KIRKPATRICK:
Q. It doesn't say "grossly contaminated," does it?
A. Right.
Q. It doesn't say "fistula formation"?
A. I mean, I think you have to take into account just surgical principles. I think that most surgeons would know what they're talking about.
Q. You think that most surgeons would?
A. Yeah.
Q. Okay. Now, it says that postoperatively, the patient should be advised to refrain from heavy lifting and/or exercise -- examples, cycling and jogging -- for at least three to four weeks after the surgery, and intercourse after one month. Patients can usually return to normal

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activities after one to two weeks.
What is heavy lifting?
A. Well, I recommend to my patients conservatively more than 10 pounds lifting or any kind of straining that would put pressure on your pelvic floor that you can avoid.
Q. And heavy lifting and exercise, now, you don't consider vacuuming either heavy lifting or exercise, do you?
A. Well, it depends on the vacuum, yeah, it could be very heavy lifting.
Q. Okay. Do you ask your patients or when you release them from TVT-O surgery, do you ask them what kind of vacuum they have?
A. No, but I advise them to just avoid it altogether.
Q. So this non -- minimally invasive surgery that allows women to return to normal activities quickly means that you they can't vacuum for a month?
A. Yeah.
Q. And you tell your patients that?
A. Yeah. Avoid housework.

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Q. What else do you tell -- avoid housework, okay. Can they do the dishes?
A. Yeah. That's not straining their pelvis.
Q. Can they make their bed?
A. That depends. If they have a high bed, it's difficult to make, it may be too much strain.
Q. And you tell them to restrain from that for a period of --
A. I tell them six weeks.
Q. Six weeks?
A. Uh-huh, just to be super conservative.
Q. Okay. What else do you tell them that they can't do?
A. I tell them not to have intercourse for six weeks. I tell them to avoid any straining, cycling, that will put pressure on the pelvic area, squats.
Q. Can they walk?
A. They can walk, they can go upstairs slowly, if they, you know, just are cautious. They can ride in the car. I tell

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them not to drive a car for the first three days. They can ride in a car and they can go back to work at three days if it's a desk job or not too strenuous, if they feel up to it.

Q. Okay. So what about a physical therapist? When would you advise a physical therapist to go back to work?

A. Depends on what she's doing, but I'd probably advise for her to -- you know, if she's an aquatic physical therapist, to wait about a week or two before she gets back in the pool. It depends on what she's doing with her patients, too. If she's actively exercising, I would want her to avoid anything strenuous with that.

Q. Okay.

A. But if she's just, you know, kind of assisting them, watching them, that would be fine.

Q. Okay. And you consider all of those things to be either heavy lifting or exercise or something that would place too much strain on the pelvic floor and could affect the sling itself?

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A. Yes.

Q. Okay. You also see here that Ethicon talks about transient leg pain lasting 24 to 48 hours may occur and can usually be managed with mild analgesics. Do you see that?

A. Yes.

Q. Now, does that basically mean you should take some Motrin or some Advil if you have some of this transitory pain?

A. That's typically what mild analgesic would mean, Tylenol, ibuprofen.

Q. And it specifies 24 to 48 hours, correct?

A. Yes.

Q. And you will agree with me that Ethicon obviously believed this was important information to put in the IFU to give to physicians, and therefore --

(Knock on door, brief interruption.)

(Discussion off the record.)

BY MS. KIRKPATRICK:

Q. So you'll agree with me,

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Dr. Pramudji, that this was information that Ethicon deemed to be important to put in the instructions for use, correct?

A. I would think so, yes.

Q. Okay. Do you see anywhere in here that they warn -- well, let me ask you this: What was the source of the 24- to 48-hour transitory leg pain?

A. I'm not exactly what source they used for that but there's a few studies that show that, you know, for the most part, it is transitory leg pain.

Q. And you don't know what causes it?

A. Oh, you mean what causes it.

Q. Oh, yes.

A. Oh, I'm sorry, I thought you meant what they were citing.

Q. Oh, no, no, what causes it.

A. I apologize. Where the helical trocar passes through the obturator foramen, through those muscles that we talked about earlier, they get irritated or maybe a nerve root gets irritated, and we believe that's

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what causes the leg pain.

Q. What nerve -- can you tell me, what muscles were those?

A. The -- just the obturator foramen muscles, there's four or five.

Q. Okay. In what percentage of cases do you see the transient leg pain lasting for 24 to 48 hours? How many women experience that as a complication of the surgery?

A. In my practice, you mean, or --

Q. Well, why don't you give me your practice and also tell me what your understanding is from the medical literature.

A. I think the studies show, you know, a range of values. It went up to -- like the Tang study, it was like a quarter of patients and some of them are less, around 6 to 10%. I would say, you know, probably somewhere in there would be a good number.

Q. Okay. So somewhere from 6% to 24% --

A. Uh-huh.

Q. -- I think is what we had.

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Now, do you see anywhere in this IFU that Ethicon informs physicians that patients can experience chronic pain after insertion of the transobturator device?

MR. SNELL: Form.

Go ahead.

A. I don't think it's specifically laid out, but they talk about the irritation and inflammation and it's sort of a known fact of surgical training that that can occur after any surgery, to have chronic pain. So it's kind of a commonsense knowledge of surgeons.

BY MS. KIRKPATRICK:

Q. Does it say anywhere in this IFU that one of the complications of this can be dyspareunia?

A. I don't think it specifically says that.

Q. Okay. Does it say anywhere in here that there can be chronic pain in the wall of the vagina for women who get this?

A. I don't believe it does.

Q. So the only pain that Ethicon

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identified is this transient leg pain, and surgeons would know about that too, correct?

MR. SNELL: Form.

A. Well, I think because, as you mentioned before, we don't typically go into the obturator canal before this procedure actually came out so that would be something that they would want to highlight for physicians so they didn't think, oh, did I do something wrong.

No, it's just sort of the anatomy there. It's a sensitive area and patients will have leg pain, but it is typically almost all the time transitory.

BY MS. KIRKPATRICK:

Q. Does it tell -- it tells physicians in here how to manage this transient leg pain, correct?

A. It does say to manage it with mild analgesics.

Q. Does it tell physicians anywhere in here how to manage chronic pain that may result from the use of a TVT-O device?

A. No, it doesn't.

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Q. Does it tell physicians in any way that women may be required to take narcotics to manage pain following -- chronic pain following a TVT-O implant?

A. No.

Q. Does it tell physicians that they may have to be on prescription medication for a significant period of time to control chronic pain?

MR. SNELL: Form.

Go ahead.

A. No.

BY MS. KIRKPATRICK:

Q. Does it tell physicians anywhere in here how to manage or treat women who have dyspareunia as a result of the TVT-O implant?

A. No, because again, common sense with pelvic floor surgeons, they're going to know about all these things ahead of time.

Q. Okay. So you think that everything is known about, except for this transient leg pain, this is the only thing that physicians need to be instructed about concerning the TVT-O device?

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A. Well, what -- I think that that's one thing that's unique to the procedure, that surgeons may not have been able to anticipate because they don't work in that area commonly.

And so, like I said, the first time it happens to you, you may think, oh, my gosh, you know, what did I do. And then -- if they didn't tell you about this, but then you realize, okay, that can occur, it's been seen, it's not just me, and it can be managed this way.

Q. Okay. How many women who have a pubovaginal sling have you seen who have chronic pain?

A. Well, I haven't seen that many patients with pubovaginal slings. I have one right now, actually, though, that has chronic pain.

Q. What kind of pain does she have?

A. She has lower abdominal pain.

Q. And what's the source of her pain?

A. She had an MRSA infection after

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the surgery.
Q. Okay. So is it the MRSA the source of the infection or is it the pubovaginal sling itself?
A. I don't know exactly. It could be the inflammatory response to the infection, it could be the surgery itself. It's hard to know.
Q. Do you think that that will be chronic pain?
A. I don't know yet. It's hard to say.
Q. How long has she experienced it for?
A. It's been about three or four months.
Q. And you haven't been able to cure that?
A. Huh-uh, not yet.
Q. Have you sought out any advice from fellow physicians on how to deal with it?
A. No.
Q. Have you talked to anyone who

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does a lot of pubovaginal slings and ask them if they have had this experience before?
A. No.
Q. You've been using a lot of anatomical terms, and I think you've been trying -- doing a very good job of trying to teach me anatomy, but I just want to make sure that we are all on the same page.
So I'm going to mark this as Exhibit 10 and ask you to help me out here a little.
(Whereupon, Exhibit Pramudji-10, Pelvic Illustration with Handwritten Labels, was marked for identification.)
BY MS. KIRKPATRICK:
Q. Okay. Can you, to orient us, this -- is this the view of a woman who you're looking up towards her pelvic area, correct?
A. Uh-huh.
Q. So this is the view that you would have during --
A. This is looking down from above. It is looking into the pelvis from above.

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Q. Into the -- okay. Can you explain that to me? Can you just label the urethra, the vagina and the rectum for me?
MR. SNELL: No. She's not here to label things on documents. She's here to give testimony. She's not labeling this thing for you.
MS. KIRKPATRICK: Well, yes, she is. This is a deposition.
MR. SNELL: No, she's not.
MS. KIRKPATRICK: Let's call the Court.
MR. SNELL: Call the Court. This is not a labeling session. She's here to answer your questions.
BY MS. KIRKPATRICK:
Q. Well, I'll tell you what. Why don't you point it out to me and I'll label it and you tell me if I'm incorrect where I've labeled the information.
MS. KIRKPATRICK: Can we do it that way?
MR. SNELL: I have no problem with that. I have no problem with that,

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but she's not here to write any labels.
MR. WALLACE: Can you -- I'm sorry, I'll sit down.
MR. SNELL: It's a deposition. It is a deposition. It is a question-and-answer session.
MS. KIRKPATRICK: It's absurdity, but, you know, we can deal with people like that.
A. So this is from the bottom. This is if you take out all the organs and look from above.
BY MS. KIRKPATRICK:
Q. Okay. So, hang on. Let me just make sure that you and I are oriented to the same place in the anatomy, and then I want to ask you about your report.
A. Uh-huh.
Q. So can you point out to me where the urethra is?
A. Uh-huh.
THE WITNESS: Can I see your pen for a second?
BY MS. KIRKPATRICK:

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Q. And by the way, you are able to write, correct? And the only reason you're not writing here is that Mr. Snell has told you not to?

MR. SNELL: Yes.

BY MS. KIRKPATRICK:

Q. And I'm going to act as your scribe for you today, so I hope my handwriting is as good as yours.

A. It's this one right there.

Q. This line here, okay. So I have labeled the urethra here where you told me to label it, right?

A. Uh-huh.

Q. And then where is the vagina?

A. Right here.

Q. Have I correctly labeled the vagina where you pointed it out to me?

A. Uh-huh.

Q. Okay. And then can you point at the rectum for me?

A. Right here.

Why do you want to do this?

Q. Because I want to ask you about some of Ms. Huskey's anatomy so I just want to make sure that we're all talking about the same thing here.

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A. Okay.

Q. Okay. So those are basically stacked on top of each other. Is that right?

A. Uh-huh, correct.

Q. Okay. And what I'm pointing at here, there's a number of muscles that are identified here. Can you tell me what muscles those are?

A. Sure. This is the puborectalis.

Q. This muscle down here, so if I label this here -- can you spell that for me?

A. P-U-B-O-R-E-C-T-A-L-I-S.

Q. Okay. And then what is this muscle? Is this a separate muscle?

A. Uh-huh.

Q. Okay. And what muscle is that?

A. That's going to be the ischiococcygeus.

Q. Okay. You're going to have to help me out there.

A. I-S-C-H-I-O-C-O-C-C-Y-G-E-U-S.

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Q. Did I get that right?

A. Uh-huh.

Q. And did I label those two muscles correctly?

A. Yes.

Q. Okay. And is this here -- this almost looks like a triangle to me, is this a separate muscle?

A. Yes.

Q. Okay. And what is this one?

A. That is going to be the -- I believe that's the iliococcygeus.

Q. I-L-L?

A. I-L-I-O.

Q. Oh, I-L-I-O?

A. Uh-huh, C-O-C-C-Y-G-E-U-S.

Q. Okay. And what is this muscle right at the bottom here?

A. That would be the -- I can't remember at the moment.

Q. Okay. I'll just put a question mark there. And then --

A. This would be the ischial spine.

Q. I-S-C-H-I --

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A. A-L.

Q. -- A-L?

A. S-P-I-N-E.

This would be the ATFP.

Q. And can you tell me what that is?

A. Arcus, A-R-C-U-S, tendineus, T-E-N-D-I-N-E-U-S -- E-U-S.

Q. Okay.

A. -- fascial pelvis.

Q. Okay. I will take credit for any spelling errors on this.

A. This is the obturator fascia that they're showing.

Q. Okay.

A. Obturator foramen.

Q. And that's where --

A. Where you want to avoid with the helical trocar.

Q. You want to avoid the obturator foramen?

A. Oh, yeah. That's where the main branches of the -- that's where the nerves are.

Q. Okay. And what is this up here?

A. The pubic symphysis.
Q. And that's a bone, correct?
A. It's a connective tissue.
Q. Okay. And then I don't know if it's labeled here. What is this here?
A. That's the pelvic bone.
Q. The pelvic bone.
A. Uh-huh.
Q. Okay. And I think we labeled this up here, but what is this structure down here?
A. That's the perineal body.
Q. Now, these muscles that you've identified for me, which of them are considered part of the levator muscles?
A. All of them.
Q. Okay. So all of these muscles, which would include the puborectalis, the ischio- -- help me out here?
A. -- -coccygeus.
Q. Okay. The ischial spine. Is that right?
A. That's the point on the bone.
Q. Okay. The iliococcygeus and then

these muscles down here, this all forms the levator muscles that support the pelvis, correct?
A. Correct.
Q. Okay. So which of the muscles -- which of Mrs. Huskey's muscles on exam, I think you indicated that she had levator muscles that were spasming. Can you show me which ones those are?
A. Right back here. Spasm right there and it's kind of tilted I think because of her SI joint problem, so you can see the sling would have been like this, and this muscle here is what's in spasm.
Q. Okay. So what you drew up here, this top line here, this is the sling placement?
A. Uh-huh. Yes.
Q. And this is the point of the muscle spasm. Is that right?
A. Yeah, right here. It's a band. You can feel it going across the left side of her vagina. This is left and this is right.
Q. Okay. So this is also the

location that you have indicated that you feel the -- I don't know exact -- I've got to go back and take a look at it, but you felt the band of --
A. Muscle spasm.
Q. Something.
A. Yes.
Q. Okay. So in that band that you feel on the left vaginal wall you believe is a muscle spasm?
A. Yeah, it's a muscle in spasm, yes.
Q. Okay. It's a muscle in spasm.
A. Yes.
Q. Okay. And is this also the point in the vaginal wall that you found tenderness?
A. She was tender, yes, on that spot.
Q. Is there anywhere else in the vagina that she was tender?
A. She was a little tender right up under here on the left side, and you can feel a little scar tissue.

Q. Like here?
A. Uh-huh.
Q. Okay.
A. And then she was just mildly tender just everywhere.
Q. She was mildly tender throughout?
A. Throughout her whole vagina, but the main spot was here. That's what's really bothering her.
Q. Okay. So we have an area of tenderness in the vaginal wall here, and this is a muscle spasm.
A. Uh-huh.
Q. Okay. Can you -- I just don't want to misrepresent in any way what you've testified about. Can you just double-check that I have labeled all of that accurately?
A. Yes.
Q. Okay. I just want to make sure we're all on the same page when we start talking about lefts and rights and anteriores and posteriors.
Okay. So looking at -- you reviewed, I think we talked about, the

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depositions, you reviewed certain medical records and you also did an IME on Mrs. Huskey, correct?
A. That's correct.
Q. And you'll agree with me that prior to the implantation of her TVT-O, she was a very active woman, correct?
A. Yes.
Q. She exercised frequently?
A. She -- I don't know how often she exercised, but she said she would do the elliptical for eight miles is what she told me.
Q. Okay. And do you remember seeing in the medical records or the depositions that she would do that three to four times a week?
A. Yeah, I think I do remember that, now that you mention it.
Q. And she had also a fairly physically demanding job as a physical therapist, correct?
A. Yes.
Q. And she, prior to the surgery,

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was able to have intercourse with her husband?
A. Yes.
Q. Correct?
And did you see in anything in her medical records prior to the implantation of the TVT-O device that Mrs. Huskey was in any way chronically physically limited in her ability to engage in daily activities?
A. No, I don't believe I did. She had some chronic complaints, but I don't -- there wasn't a limitation there.
Q. Okay.
A. She had chronic back pain, I believe she had some dyspareunia and some pelvic pain, especially on the left. But there wasn't a limitation.
Q. So she had -- so let's go through the prior conditions that you've noted. You said she had chronic back pain, she had dyspareunia. Do you believe that that was -- did you see reports of chronic dyspareunia?
A. I can't remember how long that it went on ahead of time, but it was something

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that she had been dealing with.
Q. Okay. And then, I'm sorry, I missed the last one that you had said.
MR. SNELL: Pelvic pain, it says.
MS. KIRKPATRICK: Pelvic pain, thank you.
BY MS. KIRKPATRICK:
Q. And she had reports of pelvic pain. Did you see any reports of chronic pelvic pain?
A. I don't -- I can't remember. I don't believe so.
Q. Okay. What type of pelvic pain was reported in Mrs. Huskey's medical records prior to the implantation of the TVT-O sling?
A. It was left-sided pelvic pain and some rectal discomfort and dyspareunia. And she also told me at the IME that she had some deep central pain.
Q. And you will agree that those were reported at an OR visit maybe three to four months prior to the implantation of her sling? Is that right?
MR. SNELL: Form.

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A. An OR visit?
BY MS. KIRKPATRICK:
Q. Yes. I'm sorry, ER, yes.
A. I believe so.
Q. And Dr. Byrkit, her treating physician, actually saw her at that time, correct?
A. I believe so, yes.
Q. And those symptoms resolved themselves after that ER visit, didn't they?
MR. SNELL: Form.
A. I don't know if they did or not.
BY MS. KIRKPATRICK:
Q. Okay. And do you remember Dr. Byrkit determining that those were not GYN in origin?
A. I think she thought that the left pelvic pain might have been related to the ovarian cyst at that time.
Q. Okay. Do you remember that she ruled that out after the workup in the ER and dismissed -- or discharged Mrs. Huskey and made a notation that there was no GYN origin to that particular visit, correct?

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A. Correct.
Q. And that was an acute incident, correct?
A. I believe so, yeah. But I think she had been having some complaints prior to that when she had sought care, I can't remember, it was a while back when she was concerned about her hormonal status and being evaluated for some pelvic pain and dyspareunia a couple of years before that.
Q. And you think that there was a connection between that office visit and her ER visit a few months before she had the TVT-O?
A. There could have been.
Q. Could have been, or was?
A. Pelvic pain is very -- as we talked about before, it's so complicated with the overlap of the organs in that area, I think they chalked it up, the ER visit, to diverticulosis at that time.
Q. Do you have any reason to disagree with that diagnosis?
A. No. The only thing that -- well,

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I guess I do, because when I examined her and talked to her, she has, as I mentioned in my report, she does have bladder pain and pain with filling, which indicates a possible chronic bladder disorder and chronic upregulation of the pelvic pain receptors.
So there could be some relationship there with how the nerves are cross-reacting and it could be something that's kind of been developing over time.
Q. And you agree with me that the nerves in the pelvis do cross-react, correct?
A. Yes.
Q. What is your definition of chronic pelvic pain?
A. Chronic pelvic pain would last -- typically we consider it, in general in medicine, more than six months, is considered chronic, and it could be any pain in the pelvic area. It may not be continuous, it could be intermittent, but it's anywhere in the pelvis that could be coming and going for at least six months.
Q. Okay. And in your practice as a

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urologist, what do you treat that can be the causes of chronic pelvic pain?
A. I treat interstitial cystitis, pelvic floor muscle dysfunction or levator spasm, postsurgical pain from various sources. I have a few patients with dyspareunia, urogenital atrophy, urethritis, kidney stones or ureteral stones, to be precise.
Q. Anything else?
A. Those would be the main categories of patients that I can think of.
Q. Okay. So I want to go back for a second to dyspareunia. Dyspareunia is generally a symptom of some type of pelvic pain, correct?
A. Correct.
Q. And what are the causes of dyspareunia that you treat in your practice?
A. Uh-huh. Urogenital atrophy, interstitial cystitis, urethritis, pelvic floor muscle spasm.
Q. Anything else?
A. Postsurgical scarring. That's

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all I can think of at the moment.
Q. Okay. Did Mrs. Huskey have urogenital atrophy?
A. Yes.
Q. Do you think that's the cause of her dyspareunia?
A. I don't think it's the main cause, but I think it's probably contributing.
Q. How do you treat dyspareunia caused by urogenital atrophy?
A. Typically use either vaginal estrogen cream or tablets, or there's a new medication called Osphena that I've used, O-S-P-H-E-N-A, that I've used a couple of times. It's new.
Q. Do you believe that Mrs. Huskey's dyspareunia is caused by postsurgical scarring?
A. I think some of it is, but no. Most of it's the levator spasm that she has.
Q. Okay. So when you say some of it, is the postsurgical scarring would be secondary to either the TVT-O implant,

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explant or both, correct?
A. Correct.
Q. And you'll agree with me that that surgery has caused some scarring in her pelvis?
A. It has minimal scarring right under the urethra.
Q. And that that postsurgical scarring can be a cause of her dyspareunia, even if it's not the main cause, correct?
MR. SNELL: Form.
A. It's such minimal scarring, it's possible, but it's very unlikely. I think if someone didn't know she had surgery and examined her, they wouldn't be able to really tell any difference.
BY MS. KIRKPATRICK:
Q. Okay. Do you -- so let's talk about the pelvic floor muscle spasm. That is the levator muscles, correct, throughout the entire pelvic region. And you've identified Mrs. Huskey's muscle spasm as occurring on the left -- basically the left wall of the vagina, correct?

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A. Yes. Left posterior wall. And it's abnormally angled.
Q. The muscle is abnormally angled?
A. Yes.
Q. Okay. And this muscle spasm that you say you believe that that is a cause of her dyspareunia, correct?
A. That's where her pain is coming from.
Q. Okay. What's the cause of that muscle spasm?
A. That muscle spasm, I suspect it's related to the SI joint issue that she has causing pelvic tilt. She wears a belt all the time. She has a slightly abnormal gait. I don't know if that goes back to the motor vehicle accident she was in. And I think just the overall upregulation in her pelvic area, I think the stress, that's where she's carrying her stress that she's under. You know, it's like some people carry it in their neck muscles where they'll get a tight neck or a headache, some people carry it in their pelvic floor muscles, that's where their

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stress will manifest, and she's a very stressed person. Seemed somewhat depressed, in my opinion. And so I think that's exacerbating it, not causing it but exacerbating it.
I do not think it's from the sling, because it's just not anywhere near where the sling traverses and, really, that was not really described in her medical records or by her until after the sling was actually explanted.
Q. Okay. So let's talk about this in a little more detail. Now, these muscles that we've identified here, where do they insert?
MR. SNELL: Form.
A. What do you mean?
BY MS. KIRKPATRICK:
Q. Do they insert into the bones, do they insert -- where do they go?
A. Well, you can see on the picture right there where they go.
Q. Is this the end of the muscle?
A. Yes.

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Q. Okay. So the muscle ends here and it's connected to what?
A. The bones and the ligaments right there.
Q. These bones and ligaments, the pubic bone here, and which ligaments are these?
A. That's the ATFP and the obturator fascia.
Q. And the sling itself goes through the obturator fascia, right?
A. Yes.
Q. Okay. And that's actually how it's implanted, correct?
A. That's how it's -- what do you mean, that's how it's implanted?
Q. Through the fascia?
A. That's the design of it, to go through that --
Q. Yes, thank you.
A. -- fascia and through those muscles.
Q. Okay. And what we know from Dr. Siddique's report is when he went in to

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remove her sling, he pulled down on it, as you said, right, and then when he let go, he described it as retracting behind the pubic bone, correct?
A. Yes.
Q. So we know that there's some portion of the mesh that still exists in this location through the obturator foramen and back behind this pubic bone, correct?
A. Correct.
Q. And that's the same obturator foramen that the muscles, the levator muscles, insert through, correct? Or attach to?
A. Not really. I mean, you can see where they sort of --
Q. Show me where that is.
A. They sort of come over here to this point, but then they end and they're not really near this fascia here, these muscles.
Q. How much distance is there between that -- this muscle here and that fascia there? How many centimeters is that?
A. Well, the fascia goes right up to

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that point and then the muscles start.
Q. And they're all connected, correct?
A. Yeah. They're opposing to each other, they're not necessarily connected but they're in the vicinity of each other.
Q. Okay. And they work in conjunction with each other, don't they, to perform --
A. This is kind of a separate compartment but this works as a floor. This all works together. But the obturator is a separate --
Q. Okay. And I'm sorry that you're giving me an anatomy lesson.
A. That's okay.
Q. But I'm trying to understand here. Does this muscle connect to this fascia or not?
A. The fascia --
MR. SNELL: Form.
A. -- condenses right there and makes a line and it attaches to that line.
BY MS. KIRKPATRICK:

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Q. Okay. So this is the fascia --
A. But that line is like a wall that -- kind of a partition between the two compartments. These are considered different compartments.
Q. But they're attached, correct?
A. They're attached.
Q. So this muscle attaches to this fascia here, and the sling, when it's implanted, goes in through the levator muscle here and it goes into the fascia as well, correct?
MR. SNELL: Form.
Go ahead.
A. Yes.
BY MS. KIRKPATRICK:
Q. Now, putting aside this muscle spasm here, you said there's a point of tenderness that we've identified on this right here. What do you think is causing that tenderness?
A. She's got some scar tissue right under there.
Q. And is that scar tissue from the

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implant or explant surgery?
MR. SNELL: Form.
A. Yes.
BY MS. KIRKPATRICK:
Q. Okay. And you believe that that is the cause of the tenderness that she's feeling in this --
A. That one spot.
Q. -- one spot?
A. Yes.
Q. And it's the spot that sits between the urethra and the vagina, correct?
A. Correct.
Q. Okay.
A. It's kind of right on the vaginal wall. There's a little bump, and that's where she's tender.
Q. Okay. She's tender on that. And that is also contributing to the dyspareunia that she experiences, correct?
A. It's hard to say. It could be.
Q. Okay. At least --
A. I mean, if that's all she had --
Q. I'm not asking you if it's the

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cause, the only cause, the only thing that's giving her discomfort, but that's something that's contributing to the dyspareunia and the discomfort that she's having vaginally, correct?

MR. SNELL: Form.

A. It could be, yes.

BY MS. KIRKPATRICK:

Q. Okay. So let me go through with you, then, this area of muscle spasm. I want to just do a timeline so I can understand, in my mind, how this would work.

Now, you'll agree with me that she didn't have any reports of any muscle -- do you need to take that?

A. Yes. It's one of my partners.

MS. KIRKPATRICK: Sure. No problem. We'll take a five-minute break.

(Recess, 2:31 p.m. to 2:50 p.m.)

BY MS. KIRKPATRICK:

Q. So I want to go through some of the other -- the history and get a timeline from you of when Ms. Huskey had certain issues.

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A. Okay.

Q. So I think some of the issues that you had talked about that you thought were important or relevant to the diagnosis of pelvic pain here were the back surgery that she had?

A. Uh-huh.

Q. When did she have that back surgery, do you remember?

A. She had two. She had one I believe in '97 and one in 2000.

Q. '97 and 2000.

A. Uh-huh.

Q. And was that her upper, her middle or her lower back?

A. Lower back.

Q. Okay. Do you believe that the back surgery that she had in 1997 and 2000 has any correlation or any connection to the pelvic pain that she's currently experiencing?

A. I'm not -- I'm not sure about that. It's a possible etiology. I think her pain is multifactorial. It's hard to really

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dissect it out completely.

Q. Okay, so hard to dissect out.

But would you agree with me that you can't say to a reasonable degree of medical certainty that the back surgery in 1997 is causally related to her current pelvic pain issues?

MR. SNELL: Form.

A. I can't say that it's not either.

BY MS. KIRKPATRICK:

Q. Okay. But I'm asking if you can say that it is.

A. I can't say one way or another.

Q. Can't say one way or the other, okay.

A. No.

Q. You also had referenced a shoulder injury. Is that right?

(Brief interruption.)

MS. KIRKPATRICK: I'm sorry, that's me. I'm sorry.

BY MS. KIRKPATRICK:

Q. I thought you had referenced another surgery that she had. Am I incorrect

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in that?

A. No, I didn't.

Q. Okay, no other surgery.

And when you say that her pelvic pain is multifactorial, I just want to make sure that I have a complete, full listing of each of the things that you believe are contributing to her current pelvic pain.

A. The diverticulosis -- well, number one at the top would be the levator spasm.

Q. And you believe that the cause of the levator spasm was the S1 joint issue?

A. I think that might be contributing, because, like I said, it's abnormally angled. I think she might have some pelvic tilt issues.

Q. Okay. Anything else -- let's take the levator spasm first. Anything else that you believe can be causing the levator spasm?

A. Well, like I said before, it can be exacerbated by stress, can cause a muscle spasm. The pain, you know, just the chronic

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pain, the pelvic surgery can -- any pelvic surgery can contribute but the pelvic surgery she had could contribute.

Q. Okay. Anything else? We've got the pelvic surgery, that's the TVT-O surgery. We have the potential S1 joint issue.

A. Uh-huh.

Q. Okay. We have that it may be then exacerbated by stress but not caused by stress. Is that right?

A. We don't really know for sure how it all interplays, nobody has been able to quite figure that out. I mean, I've seen patients before that it just occurred at the time of stress, there was no inciting factor. They just had a lot of stress and then they developed this pelvic floor spasm.

Q. Okay. Anything else that you think is a cause of the levator muscle spasms that she is experiencing?

A. I know she's had also some problems with rectal pain with the diverticulosis and there might be some interplay there as well. But it's one of

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those areas where usually you can't figure out exactly what causes it.

Q. So am I correct in saying that your opinion is that there's not a single cause to the muscle spasm that she was experiencing, but there are multiple causes that working in connection with each other are causing this muscle spasm that she's having? Is that right?

A. Correct, uh-huh.

Q. And then that muscle spasm that she's having is the source of most of her both dyspareunia and chronic pelvic pain that she's currently having?

A. Correct.

Q. Okay. And you gave me then a list of the issues or a list of the conditions that you believe were all working in conjunction with each other to cause this levator muscle spasm?

A. Correct.

Q. Is that right?

A. Yes.

Q. Okay. So what's not on that list

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is the back surgery from '97 to 2000. Is that right?

A. Uh-huh.

Q. Is there anything else -- okay. So that's the levator spasm.

A. Uh-huh.

Q. Then separate and apart from that, you talked about the diverticulosis, right?

A. Uh-huh.

Q. And that was the diagnosis that she had when coming from the emergency or from her emergency room visit, I believe it was the December time frame?

A. 2010, yes.

Q. December 2010, okay. And you will agree with me that at that time, her treating gynecologist ruled out a GYN origin to that particular lower quadrant pain?

A. I'd have to look at the records again. I can't remember exactly what her conclusion was about that, but I do recall that the overall thought was that it was the diverticulosis because it was more on the

Page 200

left.

Q. Okay. And you also recall that there were reports in her medical records after that, that she controls the diverticulosis by a diet and she's also, I believe, on MiraLAX. Is that correct?

A. Yes.

Q. Okay. And is there any report after December of 2010 that leads you to believe that the diverticulosis is not being controlled by the measures that she's currently taking?

A. There was -- there was a time when she was concerned about the diverticulosis flaring up.

Q. Okay. And when was that?

A. I don't remember, 2012 or '13. I can't recall. She was going to see her GI doctor.

Q. And will you agree with me that when you have diverticulosis, it is, as you termed it, you generally have a flare-up? Is that right?

A. Typically.

Q. And then it's typically controlled by your diet, by exercise, and by medication after that. Is that right?
A. Well, yeah. Keeping the bowel movements moving. She has chronic constipation, so, you know, it's hard to know how often it's contributing to her pain and discomfort because she doesn't keep it managed very well at all times. She doesn't have bowel movements regularly every day.
Q. Okay. And that's even more difficult for her now since she's not exercising like she used to, because that helps keep your bowel movements regular, correct?
MR. SNELL: Form.
A. It does in most people.
BY MS. KIRKPATRICK:
Q. And actually, she has reported that that was helpful to her at a particular period in time in keeping her bowel habits regular, do you remember?
A. I don't recall reading that.
Q. You don't recall reading that?

A. No.
Q. Did you ask her anything about it at your --
A. No, we didn't talk about that.
Q. But based on your review -- I should say this: At the examination, you didn't think that the diverticulosis or the chronic constipation were important enough to address with Mrs. Huskey at the IME, correct?
A. We did address it. We didn't go into detail with it.
Q. Okay. You didn't think it was important enough to go into detail with her about it at that time, did you?
A. Yes. And she didn't mention anything more about it either.
Q. And there were other issues that you considered to be more significant to the diagnosis of the pelvic pain than those particular issues, right?
A. Correct, uh-huh.
Q. So we talked about the levator spasms. Let me ask you this: This S1 joint issue, because I think I've asked you -- let

me get back to this.
When did Mrs. Huskey first treat for S1 joint issues?
A. I'd have to refresh my memory by looking at the medical records. I don't recall.
Q. Do you remember generally that it was significantly before she had the TVT-O sling implanted?
A. I don't. I really don't recall. I'd have to look.
Q. And do you recall that she had been treated for several years on and off for that condition?
A. That's my impression, yes.
Q. Okay. And the SI issues that she had been treating for had never, during the entire period of time that she was treating for them, caused a levator muscle spasm, correct?
MR. SNELL: Object to form.
A. I don't -- I don't know.
BY MS. KIRKPATRICK:
Q. Okay. You didn't see anything in

her medical record that indicated the type of muscle spasm that we're seeing today and the tenderness in the vagina, she had ever experienced anything like that before, correct?
A. There was nothing like that documented until after the explant.
Q. Okay. So if it is the SI joint issue, she treated for many years with that without having this type of issue, and it didn't come to pass until I think it was about six weeks after she had the explant surgery? Is that right?
A. Correct.
Q. Okay.
A. But oftentimes joint issues like that are progressive and things can shift. I don't -- like I said, I don't know if that's the exact cause, but that could be contributing.
Q. Okay.
A. It certainly -- as I said, that muscle is abnormally angled, it is not in the normal position that I've seen in other

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patients, and that would make the most sense, that things are -- her pelvis is tilted.
Q. How many women in the general population have a tilted pelvis?
A. I don't know.
Q. Is it a fairly common condition?
A. No.
Q. It's not?
A. No.
Q. Okay. Apart from -- I want to get back to this multifactorial pelvic pain. We dealt with the pelvic pain caused by the levator spasm and I think that was, again, multifactorial. There's several conditions that were kind of coming together that caused that spasm, correct?
A. (Witness nods head.)
Q. And then she's also having pain because of the diverticulosis, we talked about that. And then we also had previously talked about this point tenderness between the urethra and the vagina.
Apart from those three issues, is there anything else, in your mind, that is

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the cause of any of the pelvic pain that she's experiencing?
A. The urogenital atrophy.
Q. And what kind of pelvic pain do you think the urogenital atrophy is causing?
A. I think it's causing just general tenderness in the area, from the tissues being a little thinned out.
Q. Okay. Anything else?
A. I don't think she's ever had a laparoscope to rule out endometriosis. That's on the differential. It doesn't sound like endometriosis but it's something that would be on a long differential diagnosis list.
Q. Okay. So let's talk a little bit about endometriosis. Can you tell me what that is? You're better qualified than I am.
A. Yes. It's abnormal endometrial tissue in the pelvic cavity.
Q. Okay. And endometrial tissue is basically the uterine lining, correct?
A. Correct.
Q. And it's when the uterine lining

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is not contained to the uterus itself but also grows outside in tissues in the pelvis.
A. Yes.
Q. What is the treatment for endometriosis?
A. Well, either ablation of the lesions in the pelvis laparoscopically by burning them, cauterizing them, or hormonal therapy.
Q. Okay. And isn't one way that you deal with endometriosis is through a hysterectomy?
A. Sometimes that can be done.
Q. Okay. And at the time that you have a hysterectomy performed, a physician would be able to see if the endometrial lining was growing outside of the uterus, correct?
A. Depends on how the hysterectomy is performed. If it's a vaginal hysterectomy, they probably wouldn't be able to see anything.
Q. Okay. But you'll agree with me that the removal of the uterus or the

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hysterectomy is one way of dealing with problems related to endometriosis, correct?
A. It is, but patients can still have endometrial tissue outside that was not recognized and can still be problematic.
Q. That's basically hypothetical. You haven't seen any evidence in Mrs. Huskey's medical records at all that she had any problems with endometriosis, correct?
MR. SNELL: Form.
A. I don't -- I can't recall if that was addressed by one of her gynecologists right off the top of my head. I just kind of have that in the back of my mind on the differential diagnosis.
BY MS. KIRKPATRICK:
Q. Okay. And you know that she's had a hysterectomy?
A. Yes.
Q. Okay. And you didn't note anything in the medical records, the hysterectomy or at the time of the hysterectomy that there was any concern with endometriosis?

A. Correct.
Q. And that wasn't the reason for the hysterectomy?
A. Right.
Q. Okay. So you can't point me to anything in her medical records that would support the hypothesis that she has -- she may have endometriosis, correct?
MR. SNELL: Form.
A. Only the pelvic pain would be the only thing that would be a possible symptom of it.
BY MS. KIRKPATRICK:
Q. Okay. You will also agree with me that at the time Mrs. Huskey had her hysterectomy, she had -- it was observed that she had normal ovaries at that time, correct?
A. I'd have to refresh my memory on that.
Q. Okay. And generally, you would also agree with me that if you can visualize the ovaries at the time of a hysterectomy and that's reflected in her medical records, it's a good indication that you can visualize the

pelvic cavity and see whether there's any problem with endometrial tissue, correct?
MR. SNELL: Form.
A. Sure.
BY MS. KIRKPATRICK:
Q. Okay. And are you aware of any reports in the medical literature or any reports elsewhere of endometriosis developing for the first time after a hysterectomy was performed?
A. No, I'm not aware of that.
Q. Okay. So anything else that you believe is contributing or causing pelvic pain for Mrs. Huskey?
A. No.
Q. Okay. Now, I think you testified that -- and it's actually in your IME as well -- that Mrs. Huskey had some relief of the pain following the -- immediately following the removal of the sling, correct?
A. Correct.
Q. And that was for a period of about six weeks after the surgery?
A. Correct.

Q. And it was when she went back to have a pelvic exam done when the speculum was put into her vagina, it caused -- or I shouldn't say -- it triggered pain in the vagina. Is that right?
A. Leading up to the surgery that Dr. Siddique did, she had kind of deep central pain and pain around the area of mesh exposure, where it was rubbing, causing an irritation there. That's what she described. That's what was kind of described in the medical records and with the IME.
The pain after it was removed, upon the speculum examination, was a different pain. It was a vaginal pain, a spasm pain, and that's what she's dealing with now and that's what we're observing on examination. So it changed. It was a different -- a different kind of pain, a different area of pain. You.
Know, with Dr. Byrkit's records, you know, the pain was with intercourse, there wasn't this complaint of this chronic pain other than some -- you know, sometimes

that deep central pain.
The other thing that I just thought about was on that list of the possible sources of pelvic pain, did you write down again the interstitial cystitis?
Q. No, I didn't.
A. The possibility that we talked about earlier?
Q. Okay. Great, I want to talk about that too, thank you.
A. Because when I did the urodynamics, she had pain with bladder filling, when her bladder got full, and there's not too many things that cause that. But interstitial cystitis is the main thing that causes that.
Q. Okay.
A. And it's a diagnosis of symptoms, basically. Pain with bladder filling, urgency, frequency. She doesn't really have as much urgency/frequency now, so it's a diagnosis that I would kind of watch a patient and see, maybe try some local treatments with some bladder instillations to

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calm down the bladder with local anesthetic; something, you know, not too invasive to try to see if that gives her relief.

But that said, you know, if she does have interstitial cystitis, that would definitely cause this chronic pelvic pain, that deep central pain that she's described to me and to others, and oftentimes, that goes hand-in-hand with levator spasm, where they both kind of interplay with each other.

Q. Okay. So let me -- so there's pain when her bladder fills, but that's different than the tenderness between her urethra and her vagina and that's different than the muscle spasm, correct?

A. Correct.

Q. And that's kind of what we talked about before when women can tell the difference, for example, between a urinary tract infection and menstrual cramps.

A. Right.

Q. So that's a separate identifiable source of pain for her, correct?

A. Yes.

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Q. And I think, if I'm remembering correctly, that that interstitial cystitis can be exacerbated by pelvic surgery. Is that right, the symptoms of it?

A. Yes, it can be. Uh-huh.

Q. Okay. So then the pelvic surgery that would be relevant to Mrs. Huskey's case would be two different kinds of surgeries, both the implant of the TVT-O device and the explant of the TVT-O device, correct, those two separate surgeries?

A. Yes.

Q. So those two separate surgeries could be a contributing cause of the symptoms that she experiences from the underlying interstitial cystitis?

A. It could be.

Q. If that's what, indeed, she has?

A. Right.

Q. Okay. And you're making that diagnosis based on you believe that that's a possibility, but you can't definitively say that she has it at this point. Is that right?

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A. Correct.

Q. Okay. Is there anything -- I want to make sure that I have the whole list. Is there anything else?

A. Well, scar tissue from hysterectomy is always a possibility, adhesions, but it doesn't sound like that to me. That's all I can think of.

Q. So in this case, even though it's a possibility, it does seem unlikely?

A. It's kind of further down the differential diagnosis.

Q. Okay. So then let's go back to talking about the new type of pain that she experienced. And you're not suggesting that the use of the speculum during the pelvic exam caused some kind of damage or caused some kind of muscle spasm or tenderness in the vagina, correct?

A. I don't think it caused it. Somehow it triggered that muscle to go into spasm. I don't know if it was her -- I don't know. I don't know how that happened.

Q. Okay. And so you agree with me,

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from reading her medical records, that between the explant surgery and that follow-up visit, nothing else had been in Mrs. Huskey's vagina, correct?

A. Correct.

Q. She had not had intercourse with her husband during that time, so it was really the first time that anything was introduced into her vagina following the explant surgery, that triggered both the muscle spasm and the other point tenderness that we discussed, correct?

A. As far as we know.

Q. Okay. And will you agree with me that that all -- one of the causes of that could be the pelvic surgery to remove the TVT-O device itself?

MR. SNELL: Form.

A. I don't think so, because it's in a different compartment. I mean, I suppose, just speculating, just with any surgery in that area, you know, maybe there could be a reaction there with the muscle. But it's so far away from it, I just feel like that's

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very unlikely, in my opinion.
BY MS. KIRKPATRICK:
Q. I think that we had -- so you have no explanation for why all of these other conditions which are -- you'll agree with me, are more distal in time to the explant surgery, correct? They all predated the explant surgery?
MR. SNELL: Form. Form.
A. What all?
BY MS. KIRKPATRICK:
Q. All of the other issues that we talked about. For example, she had SI joint issues before she had the removal surgery, correct?
A. Uh-huh.
Q. And she had --
MR. SNELL: Hold on. You have to say yes or no. It comes out uh-huh, huh-uh.
THE WITNESS: Yes. Sorry. Yes.
BY MS. KIRKPATRICK:
Q. I'll go back so we have a clean record on that.

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You'll agree with me that the SI joint issues predated the surgery to remove the TVT-O stress, correct?
A. Yes.
Q. And you'll agree with me that she had stress that existed before she had the removal surgery to take out the TVT-O mesh, correct?
A. Yes.
Q. And you'll agree with me that these bladder issues, to the extent they existed, predated the removal of the TVT-O mesh, correct?
A. Yes.
Q. Yet the pain itself didn't express itself until after the surgery.
A. Yes.
Q. Okay. But you don't think that the surgery, even though it was the closest thing in time, was the cause of the problems that she's having?
A. No.
Q. And you don't think it's a cause of -- in conjunction with the rest of the

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issues that she had to the problem?
A. No. I think it's way down the list as a possible cause.
Q. So it's just a coincidence?
A. I think so. I think it's a confluence of factors, and, you know, she had been -- Dr. Siddique had planted in her head that she was going to have dyspareunia and chronic pelvic pain and chronic problems, and I think that, you know, all that contributed to, and all the other factors that she had could have all contributed to make it happen.
But I don't know why making an anterior incision in the vaginal wall, removing the piece of mesh, and then she felt great afterwards, I don't know why that would cause a spasm six weeks later. That's kind of farfetched.
Q. Okay. What do you mean, "planted in her head"?
A. Well, when she first saw him, he said that, "Well, I need to remove all the mesh but you may still have dyspareunia, you will -- you may have chronic pain and

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recurrent incontinence," and, you know, she -- up till that point, she had some pain, she had dyspareunia, but that was just the mesh exposure. And I think he kind of sensitized her to that.
Q. You're not suggesting, are you, that Mrs. Huskey's current medical conditions are all in her head, are you?
A. No. Absolutely not.
Q. And they are clinically documented through your exam and through her medical records, correct?
A. Absolutely.
Q. And you're not suggesting that Mrs. Huskey is willing herself to have such bad chronic pelvic pain that she can't have sex with her husband, are you?
MR. SNELL: Form.
A. No. But you know that we're not just a body and a mind, it's all interconnected. And so if there's a -- if you're told that you're not going to get better, then you may not get better. If you're told that you're optimistic and that

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you're going to get better, then you have a better chance of getting better. It depends on your outlook, and doctors see this all the time, how patients' outlook on things will improve they're outcome.

And so I'm not saying that I'm not -- I don't know if that's what's going on here, but it could be part of it. And I think that she's got a lot of stress and depression that I don't know is adequately treated, and that is known to exacerbate chronic pain and muscle spasm, not just in the pelvic floor but in other parts of the body. Chronic back pain, we talked about migraines.

So all that is interconnected. And as a source of the spasm, I don't know if it was, but I think it can definitely exacerbate it and I see that clinically in practice. Anyone that deals with pelvic pain will see patients come in with pelvic floor spasm that's made worse by stress.

And all the stress that she's been under with this lawsuit and with her

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breast cancer, I know that's all contributing and making it harder for her. I'm not saying that that caused it and I'm certainly not saying that that's in her head.

BY MS. KIRKPATRICK:

Q. Okay. Well, let me go back to that.

This muscle spasm occurred before she was involved in any lawsuit, correct?

A. I don't know when she filed the lawsuit, but I know it's after she saw the commercials and asked Dr. Byrkit about the mesh lawsuits. So she had been -- it was on her radar.

Q. Okay. You'll agree with me, though, that if the reports of the muscle spasm and the problems predated that, that there's no correlation; you're not suggesting, are you, that Mrs. Huskey is making up any of this for the purposes of a lawsuit?

MR. SNELL: Hold on. Hold on, hold on. Form and foundation.

Go ahead.

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A. I'm not suggesting she's making it up, no. She definitely has a muscle spasm there.

BY MS. KIRKPATRICK:

Q. Okay. And you can't fake a muscle spasm, correct?

A. No.

Q. And Mrs. Huskey is not faking a muscle spasm?

A. No.

Q. Okay. So something is causing the muscle spasm that she is having, correct?

A. Yes.

Q. And she's also not faking the point tenderness between the urethra and the vagina, correct?

A. I have to take her word for that. I mean, pain on examination, tenderness, you just have to take the patient's word for it.

Q. Okay. Do you have any reason to doubt her word for it?

A. No. I think she was -- I think she was legitimate on that.

Q. You believe that she was being

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honest with you in what she was telling you during the exam, correct?

A. As far as I could tell, yeah.

Q. Okay. You have no reason to suspect that.

And in addition to that, you're not suggesting in any way that Mrs. Huskey had her sling removed for the purposes of any kind of lawsuit, are you?

MR. SNELL: Form.

A. No.

BY MS. KIRKPATRICK:

Q. And she had it removed because that was, in her doctor's estimation, what was necessary to relieve the physical symptoms that she was having, correct?

A. Correct.

Q. And you don't second-guess that opinion at all, do you?

A. No. I don't know if I would have done as extensive of an excision. I don't think she needed to have the whole thing removed. He could have left the part on the other side and she might have maintained

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continence if he had left that in place.
She was only complaining of the area where there was an exposure.
Q. But you're not second-guessing his medical judgment in performing the surgery on Mrs. Huskey, correct?
A. Right. I mean, medicine is a practice, so we have different opinions at different times. He saw the patient at that time. That's what he thought. But from what I read, it sounded like he could have just removed that area, that one area.
Q. But you haven't spoken to him about the case, correct?
A. I've read his deposition, but that's all.
Q. Right. But you haven't spoken to him?
A. And the medical record. No.
Q. And you weren't there at the time to see what she was like on examination when he saw her?
MR. SNELL: Form.
A. Right.

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BY MS. KIRKPATRICK:
Q. And you don't have a reason to second-guess that medical judgment?
MR. SNELL: Form.
Go ahead.
A. Well, he didn't -- there was no point, there was no record of tenderness on the contralateral side, so --
BY MS. KIRKPATRICK:
Q. What's the contralateral side? Can you show me on that drawing?
A. Just the other side from where the mesh exposure was. She had the mesh exposure here on the right within the vaginal wall, so -- was it the right or the left, I get confused -- but on the other side, at that time she didn't have tenderness.
MR. SNELL: If you need to look at the records, feel free to look at the records.
BY MS. KIRKPATRICK:
Q. Yeah, you can absolutely feel free to look at the records if you want to.
(Witness reviews document(s).)

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A. On the right. So he noted a 2-centimeter mesh exposure on the right sulcus, and rather than just removing that whole area, he removed the whole thing.
BY MS. KIRKPATRICK:
Q. Okay. But that wasn't for purposes of litigation, correct?
A. Correct.
Q. And can -- I think we talked about this before, but just let me make sure. The mesh is a foreign body that's implanted in Ms. Huskey's pelvis, correct?
A. Correct.
Q. And anytime you implant a foreign body into someone, it can cause a chronic inflammatory reaction, correct?
A. It's a nerve, so it causes a mild chronic inflammatory reaction. It's not significant.
Q. You believe that's not significant?
A. No.
Q. What's that based on?
A. Based on experience and on the

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literature.
Q. What literature?
A. The whole body of literature. There's not -- hasn't been problems with chronic inflammation in slings.
Q. Okay. So your opinion is that a sling cannot cause a chronic inflammatory response in a person?
A. No.
Q. Is that right?
A. That's not my opinion.
Q. Oh, okay. Can you tell me what your opinion is?
A. I said it can cause a mild chronic inflammatory response but nothing that's clinically significant.
Q. Do you believe that an inflammatory response in connection with scar tissue in the pelvis can cause pain upon bladder filling?
A. Repeat that question, please?
Q. Okay. Do you believe if the pelvis is both inflamed and has scar tissue in it, that that can cause pain upon bladder

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filling?
A. Just anywhere in the pelvis?
Q. Anywhere in the pelvis. Well, I mean, let's -- you know, where the TVT-O is placed.
MR. SNELL: Form.
Go ahead.
A. I would think it unlikely.
BY MS. KIRKPATRICK:
Q. Around the urethra and bladder?
A. It's unlikely.
Q. You think that's unlikely too.
A. Yeah.
Q. Okay. Now, you'll agree with me, though, that Mrs. Huskey has had a number of cystoscopies, correct?
A. Yes.
Q. And she's never been diagnosed with interstitial cystitis?
A. Well, it's not a diagnosis that you would make on a regular cystoscopy.
Q. She's never been diagnosed, has she?
A. No.

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Q. Okay.
A. You would have to do a hydrodistention, and even that's not 100 percent specific. Like I said, it's diagnosed based on symptoms and ruling out other disease processes.
Q. I want to talk about the speculum exam. Do you perform speculum exams?
A. Yes.
Q. About how many have you performed over the course of your medical career?
A. Thousands upon thousands.
Q. And in those thousands upon thousands of speculum exams that you've done, have you ever seen a situation in which a speculum exam triggered the type of levator muscle spasm that Mrs. Huskey is having?
A. Yes.
Q. Okay. When did you see that?
A. I've seen patients that would have severe pain afterwards and they had a muscle spasm.
Q. Okay. Severe chronic pain afterwards?

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A. Uh-huh.
Q. And it never went away?
A. Yes.
Q. Okay. How many patients like that have you seen?
A. Just a couple.
Q. Okay. And what do you believe caused their spasms?
A. Anxiety about the exam. I don't know, chronic tenderness in the area. These are chronic pelvic pain patients.
Q. Okay. So you've seen that in about two of thousands of women, right?
A. Correct, uh-huh.
Q. Okay. Have you ever seen any reports in the medical literature or anything discussing why a speculum exam would trigger a levator muscle spasm?
A. I've never seen anything like that.
Q. So it's just a couple of patients that you've seen have -- when did you see those patients?
A. I don't know. Years ago. I

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don't remember.
Q. Have you seen anyone have that reaction in the last five years?
A. I don't recall.
Q. In the last 10 years?
A. I don't know when it was, but I've seen it happen before.
Q. Can you give me a ballpark of when you saw that?
A. Maybe three or four years ago.
Q. Did either of those patients have mesh?
A. No.
Q. Do you agree with me that the TVT-O sling was the cause of the mesh erosion that was seen by both Dr. Byrkit and Dr. Siddique?
MR. SNELL: Form.
A. The sling was the cause of the mesh erosion?
BY MS. KIRKPATRICK:
Q. There's no other cause of it, the sling is the cause of the erosion?
MR. SNELL: Form.

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Go ahead.
A. And the sling was what was exposed. Whether it was the cause of it, I mean, it could have been the bleeding that she had right after the surgery, after she exerted herself and then she immediately had some significant bleeding, and it could have opened up the wound and then allowed the mesh to be exposed at that point.
BY MS. KIRKPATRICK:
Q. Okay. How many patients have you seen of the thousands that you have treated who had complications from their slings because they vacuumed?
A. Have I seen that... probably two.
Q. Two?
A. Uh-huh.
Q. Okay. And what kind of sling did they have?
A. I don't remember.
Q. Do you remember whether it was a transobturator or retropubic?
A. No.
Q. And what did you have to do after

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they vacuumed?
A. I can't remember the specifics of the case, but I can remember patients having -- coming in with problems after vacuuming. I can't remember if it was recurrence of incontinence or a mesh exposure. But I can think of specific cases where they were vacuuming and then they had problems.
Q. Now, I want to go back to this drawing again. Now, we've -- I want to make sure I'm pointing at the right place. These are the muscles and these muscles, like every muscle in the body, operate by contracting, correct?
A. Relaxing and contracting.
Q. Relaxing and contracting.
A. Yes.
Q. And they're attached here to the obturator fascia, correct?
A. No, to the arcus tendineus.
Q. Which is at the edge of that, correct?
A. Correct.

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Q. And so as this muscle or any of these levator muscles contract, they necessarily will have an effect on what you just called it that I can't quite remember.
A. The arcus tendineus.
Q. Arcus tendineus.
A. Well, the arcus tendineus is pretty well fixed, so it's designed to be there almost like a wall so that it doesn't -- it doesn't move when the muscles contract.
Q. So how do the muscles contract if they're fixed in place?
A. Well, it's just like a muscle that's fixed to the bones. The bones don't move but the muscle contracts, so it's the same thing with that arcus tendineus. It's designed to be the fixed point and then the muscles squeeze and the other organs move and the pelvic floor lifts.
Q. So the other muscles there would be --
A. The pelvic floor lifts or descends.

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Q. The others would be the urethra, the vagina, the rectum, would all move in relation to the contraction of these particular muscles. Is that correct?
A. Yes.
Q. Okay.
A. When you do your Kegels, you know, you'll feel the vagina squeezing around the -- on exam. And this is a 3D rendering. Of course -- well, it's 2D, but in 3D you've got the pelvic floor here, it's like a bowl, and then the arcus tendineus on the side and then the obturator fascia is like this.
So these may extend, but this doesn't move. It's not -- even though they're right next to each other, they're not interconnected. The obturator is a completely different compartment, even though they're right there. This is moving but this is not moving in relationship to it (demonstrating).
Q. So I think that you drew a picture of -- or I drew -- no, you drew the picture of the sling. I labeled it.

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Can you tell me what muscles a transobturator sling goes through, if any, when it's placed?
MR. SNELL: Form.
A. I'd have to look at the anatomy book because I don't have them memorized. There's four or five muscles there.
BY MS. KIRKPATRICK:
Q. And the sling is placed through those muscles, correct?
A. Uh-huh.
Q. And is it also placed through the obturator fascia?
A. Yes.
Q. Okay. And then where does it insert into the obturator space?
A. It's on the medial superior aspect of the obturator foramen.
Q. Okay. And we've noted the obturator foramen on this picture, correct?
A. I'm sorry, the obturator -- this is the obturator canal. The obturator foramen is the opening in the bone, so the sling comes through right here and then the

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obturator canal is over here.
Q. Okay. So this would be the obturator canal --
A. The obturator canal, yes.
Q. -- not the obturator foramen?
A. Yes.
Q. Okay. So it goes through the obturator foramen into the obturator space, correct?
A. Well, there's really no obturator space.
Q. Okay. I thought you just told me that the obturator space was different than the muscles.
A. Well, it's a different muscle compartment.
Q. Okay. What's the difference -- okay. Compartment, it's the obturator compartment.
A. When I was referring to the pelvic floor, is that what you're talking about?
Q. Yeah, I'm just trying to make sure we have the same terms.

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A. It's a compartment.
Q. Okay. The obturator compartment is different than the pelvic floor compartment?
A. Correct.
Q. But the transobturator sling goes through the pelvic floor muscles and the pelvic floor compartment, correct?
MR. SNELL: Form.
A. I mean, it might go through a little bit of the muscles here, there's not much there, before it gets to the obturator. These are kind of below where the sling would be, and then it would go through the obturator.
BY MS. KIRKPATRICK:
Q. Into the obturator compartment, is that right?
A. Canal, compartment, yeah.
Q. Okay. And you don't believe -- it's your opinion that a transobturator sling cannot cause a levator muscle spasm?
A. Not in that area. If anything, it would be up in here, right next to the

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urethra.
Q. So it has to be direct -- in your opinion, it has to be directly adjacent to or intertwined with the sling itself; otherwise it cannot be a cause?
A. Yeah. I don't think so. It's really far apart. You can't tell in this picture, but they're very far apart from each other.
Q. What do you mean by very -- how much is very far?
A. I mean, this far apart. That's very far apart (demonstrating).
Q. Well, can you give me an estimate of what that is?
A. 3 centimeters.
Q. Maybe 3 centimeters apart?
A. Yeah, uh-huh.
Q. So you think there's 3 centimeters difference between where the sling would have been implanted and where she's having a muscle spasm?
A. Correct.
Q. Okay.

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MR. SNELL: When we get to a good stopping point, can you just let me know? Because I've just got to go grab my bags.

MS. KIRKPATRICK: Oh, go grab your stuff, yeah.

(Recess, 3:36 p.m. to 3:52 p.m.)

BY MS. KIRKPATRICK:

Q. Okay, Dr. Pramudji. In your first report, you had notated that -- or observed that you believe that Ms. Huskey would need further therapy and medication for her pelvic pain and dyspareunia.

Do you still hold that opinion?

A. Yes.

Q. And you said that overall, her prognosis was good.

A. Yes.

Q. Do you still hold that opinion after seeing her at the independent medical exam?

A. Yes, I do.

Q. Would it surprise you to know that after you performed a pelvic exam on Mrs. Huskey, she had to be in a wheelchair?

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A. Yeah, I would be surprised.

Q. And she had to be in a wheelchair at the airport because of the severe pain that she was in?

MR. SNELL: Object to form.

A. I mean, she has a spasm there. She said it was tender on exam. I did a very gentle exam. I'm surprised that it was that bad. She didn't -- she walked out of the office and didn't seem like she was in that much pain. She was in some pain, but it doesn't seem like it warranted a wheelchair.

BY MS. KIRKPATRICK:

Q. But you did know that she was in pain when she walked out of the office after the pelvic exam?

A. She said she was in tender, that it had flared it up.

Q. And most women don't have pain when they walk out of an office with a pelvic exam, correct?

A. Correct.

Q. Now, in your second report, in your IME, you phrased your prognosis a little

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bit differently.

(Brief interruption.)

MR. SNELL: I'm sorry. Hold on.

BY MS. KIRKPATRICK:

Q. You noted that there are several treatment options that can be explored but there's hope for her to return to a satisfying and productive life.

You would agree with me that right now, her life is not particularly satisfying, correct?

A. Well, she does have some leisure activities that she participates in, but she can't have intercourse with her husband right now, which is important to her, and she says that she can't work right now.

Q. Which is also something that's very important to her, correct?

A. Uh-huh.

Q. And she can't exercise anymore, correct?

A. That's what she says, yes.

Q. So her level of activity has changed dramatically from what it was before

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the TVT-O implant, correct?

MR. SNELL: Form.

A. As far as I can tell, yes.

BY MS. KIRKPATRICK:

Q. Okay. As far as what she reports.

A. Yes.

Q. And there's nothing at all that would make you question that, is there?

A. No.

Q. Okay. And she is in a loving relationship, correct?

A. That's what she says, yes.

Q. Okay. And she also told you that she does want to be able to have intercourse with her husband, correct?

A. Yes.

Q. And she also told you that she misses the ability to have physical intimacy with her husband, correct?

A. I don't remember if she told me that directly, but I know that's what the records show.

Q. Okay. So you would agree with me

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that it's not Mrs. Huskey's choice that she's not able to have sex with her husband, correct?

MR. SNELL: Form. Form.

A. I don't know for sure.

BY MS. KIRKPATRICK:

Q. You think she might be choosing just not to have sex?

A. Some women will come up with excuses. I don't know.

Q. Do you have any reason to believe, based on what Mrs. Huskey has said to you and what's in her medical records, that she's making up excuses not to have sex with her husband?

A. I don't know. I mean, I know she's had some difficult relationships in the past. I don't know her whole past. But from what I can tell, no, she seems like she's being straight about that.

Q. Okay. And you also talk about a productive life. We talked about Mrs. Huskey isn't able to work, correct?

A. Uh-huh. Yes. That's what she

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says.

Q. And she's not able to engage in many of the activities that she engaged in both through work and through her personal life, correct?

MR. SNELL: Form.

A. I know that she enjoys her boat and she does a lot of gardening and work around the house, so she's able to be fairly active at times. I don't think it's as much as she did before. It may be different. But our lives change as we get older as well, so, you know, I think that there's a lot that she can still do.

BY MS. KIRKPATRICK:

Q. Okay. Do you think that any of the changes in Mrs. Huskey's life have occurred because she's gotten older between the time of the TVT-O implant and six weeks after the TVT-O explant?

A. Can you repeat that question?

Q. Sure. You said that things change when we get older, our lives change as we get older. That's not what's going on

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with Mrs. Huskey right now, is it?

A. I think that's obviously part of it, that she's getting older as well. But that's not the main part of it, no. I think the main thing that's holding her back is the levator muscle spasm.

Q. And the pain that that's causing her, correct?

A. Correct.

Q. What do you mean, there's hope?

A. That if she has therapy and she sticks with it, that she could have a good prognosis, that that can be resolved.

Q. Okay. It could be resolved --

A. Yes.

Q. -- but it won't definitely be resolved, correct?

MR. SNELL: Form.

A. There's no definite in medicine.

BY MS. KIRKPATRICK:

Q. Now, I want to ask you just a couple of questions about your pelvic exam of Mrs. Huskey.

A. Sure.

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Q. First of all, let me ask you this: You indicated that to Mrs. Huskey her ability to have sexual relations with her husband was important to her, correct?

A. Yes, and I believe she's sexually intimate with him, but just not with intercourse.

Q. Okay. But that intercourse is important to her, correct?

A. We didn't talk about it specifically.

Q. So you didn't ask her at the exam about her ability to have intercourse?

A. I think we talked about, you know, the intercourse that she had had over time and that right now, it's uncomfortable, but we didn't talk about how important it is to her, which was your question.

Q. Did she say it was uncomfortable or did she say it was painful?

A. She said it was painful at this point.

Q. Okay. And did she tell you that it caused her so much pain that at times it

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has caused her to cry?
A. No.
Q. Those are not normal reactions to intercourse, correct?
A. Correct.
Q. And that's not just something that you could attribute to a vaginal atrophy, correct?
MR. SNELL: Form.
A. There are a lot of women that have severe vaginal atrophy that will cause them to cry when they try to have intercourse.
BY MS. KIRKPATRICK:
Q. And that's solved when you give them generally a Premarin cream?
A. Yes, over time. It takes time for it to be effective, and sometimes they need pelvic floor therapy and stretching of the tissues and more than just the cream.
Q. Okay. But they would require treatment for that, correct?
A. Yes.
Q. You don't talk in your report

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about sexual function for Mrs. Huskey. Why not?
MR. SNELL: Form. Misstates.
A. I do. Yeah, I talk about the discomfort that she has and the pain with stimulation.
BY MS. KIRKPATRICK:
Q. When you're talking about the limitations on her life and what it is -- well, you know what, if --
(Counsel reviewing realtime transcript on an iPad.)
BY MS. KIRKPATRICK:
Q. Show me where in your report you talk about her sexual functioning in your IME.
A. You're talking about the IME?
Q. Uh-huh.
A. The second-to-last paragraph on page 1, when she had intercourse after the TVT, when she had the mesh exposure.
Q. Okay. That's where you're reciting her medical history, correct?
A. Correct. Is that what you were

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referring to?
Q. Yeah.
A. And then on page 2, the second paragraph, when she had the -- after the explant, she had painful intercourse. The third paragraph, she was able to have sex successfully two times that it wasn't horrible, so it was tolerable, it's getting better, and that was when she was actively having physical therapy, which was why I feel like there's hope for her, because when she was having therapy and doing well on the Cymbalta, she was actually doing well or getting better. She got down to a pain level of 2 to 3, I believe.
Q. Do you consider sex that's not horrible to be doing well?
A. Getting better. She was getting better.
Q. But it's not doing well, and that's certainly not the standard.
A. No.
Q. We wouldn't want to be aiming just to get her to a point that it's not

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horrible, right?
A. And I think -- that's what she told me. But I think in the medical records when it was closer to the event, that I read that it was not bad. I believe that was in Dr. Siddique's records.
Q. Not a rousing endorsement either.
A. But the point is, getting better with therapy. Not there, but improving.
Q. Okay. And in your impressions, do you comment on her sexual function as sexual dysfunction?
A. Not specifically, no, I don't.
Q. So in the two -- well, page and a half that you devote to that, that wasn't something that you believed was important enough to note. Is that right?
A. Well, I'm kind of -- in my mind, I was putting that in with the pelvic pain and the treatments for the pelvic pain and kind of putting that all together, even though I didn't specifically call it out.
Q. Okay. And -- hang on one second.
(Sotto voce discussion.)

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MS. KIRKPATRICK: I think that's all that I have.

EXAMINATION

BY MR. SNELL:

Q. Dr. Pramudji, Burt Snell. I have some follow-up questions, and why don't we kind of start where we left off, where Mrs. Huskey is right now. You saw Mrs. Huskey at the IME, correct?

A. Correct.

Q. You're aware that she has cancer, correct?

A. Correct.

Q. Can that cancer obviously have an effect on her well-being?

A. Yes.

Q. Can it have an effect on her stress levels?

A. Absolutely.

Q. Can the treatment modalities for cancer have an effect on her stress levels and her well-being?

A. Yes, she was in acute pain from the breast expanders on the day of the exam.

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She was very sensitized and almost tearful to begin with.

Q. Plaintiff's counsel asked you questions about Mrs. Huskey's claim that she cannot work. Did you see any of the doctors, her treating doctors, say that she could not work because of her sling surgeries?

A. No.

Q. Do you believe she can't work because of her sling surgeries?

A. No.

Q. Plaintiff's counsel asked you about her ability to engage in leisure activities. Do you think the sling had any effect on her leisure abilities?

A. I don't think so. I mean, she's been able to enjoy boating and gardening and house projects.

Q. Mrs. Huskey claims that she can't exercise or can't exercise as much. Do you believe that the sling had any effect or cause on that claim?

A. No. I think the muscle spasm is what's affecting her.

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Q. In your report on page 4, we were just looking at the impression section of your IME. It says "The levator pain that has occurred since the mesh was explanted was precipitated on speculum exam," and I believe you discussed that part with plaintiff's counsel, correct?

A. Correct.

Q. "And is a spasmodic pain at the posterior wall of the introitus, well away from the area of sling insertion."

Did I read that correctly?

A. That's correct.

Q. And I think you've testified to that, you can correct me if I'm wrong or not. But where her spasm and pain was is not in an area where the sling was. Is that correct or not?

A. Correct. It's too posterior to be caused by the sling.

Q. And you state "This was not caused by the sling and was precipitated on speculum examination. The primary area of muscle spasm and pain is too posterior to be

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caused by the sling."

Did I read that correctly?

A. Yes.

Q. Is that an opinion you continue to hold?

A. Yes.

Q. You hold that opinion to a reasonable degree of medical certainty?

A. Yes.

Q. Plaintiff's counsel asked you some questions about vacuuming and whether vacuuming can lead to mesh exposure. And there seemed to be some cynicism about how strenuous vacuuming was.

My question is this: Did Mrs. Huskey call in to her doctor 10 days after her surgery and report that she was having heavy bleeding?

A. Yes, she did.

Q. Did they ask her to come in and be seen?

A. Yes.

Q. And was a mesh exposure seen at that time?

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A. Yes.
Q. Is a mesh exposure a wound complication?
A. Yes.
Q. Can wound complications occur with any surgery, any pelvic floor surgery?
A. Yes. Any wound can break down.
Q. And in your initial report, you state that you believe that she had general wound healing issues which led to her exposure. Is that correct or not?
A. Yes, because of the mesh exposure, that would indicate that there was a problem with the wound healing, and I don't know how the buttonholing contributed to that or not, and then the heavy bleeding definitely, because that had to come out somewhere. It would come out of the wound, more than likely.
Q. Okay. Plaintiff's counsel -- strike that.
There was some testimony about endometriosis. Do you recall that?
A. Yes.

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Q. Is endometriosis common?
A. Yes.
Q. Has anybody ruled out endometriosis as a cause of Mrs. Huskey's pain, in your opinion?
A. No.
Q. Do you have Dr. Steege's deposition or deposition exhibits handy?
A. Yes.
Q. I believe plaintiff's counsel asked you about literature regarding how common endometriosis can be?
MS. KIRKPATRICK: Objection.
MR. SNELL: I know you did.
MS. KIRKPATRICK: I know I didn't.
BY MR. SNELL:
Q. Do you remember a doctor testifying that endometriosis is commonly seen in women with pelvic pain?
A. Yes.
Q. All right. Is that opinion based on the literature, your clinical experience, one or both?

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A. Both.
Q. Looking at Exhibit 7 to Dr. Steege's dep, it's actually an ACOG Technical Bulletin on chronic pelvic pain, and on the subject of endometriosis, it states, "It has been found in up to 48% of women having laparoscope for evaluation of chronic pelvic pain."
Do you see that?
A. Yes.
Q. What does that mean, in those women who presented with chronic pelvic pain who actually have a laparoscopic surgery, endometriosis was found in 48 percent? What's the significance of that opinion?
A. That that's very common in anyone with pelvic pain, that you need to do laparoscopy to diagnose it.
MS. KIRKPATRICK: Can I just see that before you put it away?
THE WITNESS: Yeah.
MS. KIRKPATRICK: Thanks.
BY MR. SNELL:
Q. Do you believe her back pain --

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strike that.
Has her back pain been ruled out as a cause of her pain?
A. I don't think it's been completely ruled out, no.
Q. There was some earlier questions about TVT-O and its placement and questions about placement in the vaginal wall. Let me just make sure I understand this and ask you, is TVT-O placed in the vaginal wall or behind the vaginal wall?
A. Behind the vaginal wall. You create a space between the urethra and the vaginal wall and place it in that space.
Q. Okay. One of the exhibits plaintiff's counsel marked was Exhibit 9, the TVT-O IFU from 2005, and you were asked some questions about that, correct?
A. Yes.
Q. On the first page, I'll read it to you, it states, "It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians

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in the surgical management of stress urinary incontinence and specifically in implanting the Gynecare TVT Obturator device."

Have you seen that before in the TVT-O IFU?

A. Yes.

Q. And when you earlier testified that other than mesh exposure there were overlapping complications, would these be complications that surgeons would be aware of via their medical training and schooling?

A. Yes, absolutely. Yes, we're taught about complications of pelvic surgery and other various procedures that are specific to those procedures.

Q. Where it talks -- and plaintiff's counsel pointed this out -- about how it should be placed with care to avoid vessels, nerves, discussed those nerves and other parts, is it common surgical knowledge in the types of surgeons who would be doing stress urinary incontinence that damage to nerves can lead to pain?

A. Yes.

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Q. And is it common knowledge that pain can be short-term or sometimes permanent?

A. Yes. It's very common knowledge.

Q. Did you see whether or not Dr. Byrkit relied on the IFU?

A. She did not.

Q. In response to one of your questions, I think you were cut off when you were talking about the --

MS. KIRKPATRICK: Objection.

BY MR. SNELL:

Q. -- the little piece of scar tissue under the urethra, and I wrote you stated, "If that was all she had."

You didn't finish the answer. My question to you is, were you trying to complete your answer or not?

A. What I was trying to say was that if that was all -- the only problem that she had, I don't think we would be here today. I don't think it would be a big issue for her at all.

Q. Do you think that would cause

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dyspareunia?

A. Some, but not as much at all. It would be very manageable.

Q. You were asked questions about the primary endpoint in a study. Is the primary endpoint the point by which the study is powered?

A. Yes.

Q. You've looked at a lot of literature, metaanalyses, document reviews, correct?

A. Correct.

Q. And did they assess complications and report on them?

A. Yes, absolutely. They don't just report the success rate; they go into the complications.

Q. And did you consider the data on efficacy and complications for the TVT retropubic device to be important as well in your assessment of the TVT-O data?

A. Yes, absolutely. The TVT-O is just a minor modification.

MR. SNELL: That's all I have.

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Thanks.

FURTHER EXAMINATION

BY MS. KIRKPATRICK:

Q. That's -- I just have a couple of questions for you.

Does endometriosis cause levator muscle spasm?

A. If it's severe enough, it can put their pelvic floor into spasm.

Q. If it's severe enough?

A. Uh-huh.

Q. Don't you think that it would have been diagnosed before it got severe enough to get to a levator muscle spasm in Mrs. Huskey?

A. Possibly.

Q. Endometriosis is not the cause of her levator muscle spasm, is it?

A. I don't know.

Q. Okay. You know there's absolutely no evidence in her medical record whatsoever that she has endometriosis, don't you?

A. Well, there's no -- no one has

ruled it out, either, completely.
Q. And you don't think that the visual examination of normal ovaries and the removal of her uterus are sufficient to rule out pretty conclusively that she doesn't have endometriosis?
MR. SNELL: Form.
A. Did she have a vaginal or an abdominal hysterectomy? I can't recall.
BY MS. KIRKPATRICK:
Q. Well, you tell me. You're the doctor.
A. Let me get that, because just looking at the ovaries alone doesn't rule it out. You can have implants throughout the pelvis.
MR. SNELL: Do you need Byrkit?
THE WITNESS: Yeah, I need Byrkit. That's what I was looking for.
MS. KIRKPATRICK: Here, I'm going to give you this one too, if you're looking for that.
(Witness reviews document(s).)
THE WITNESS: So far everything

just says hysterectomy.
BY MS. KIRKPATRICK:
Q. Okay.
A. I don't recall a lower abdominal incision, so I think it was vaginal, so it would be hard to see anything with a vaginal hysterectomy.
Q. One other question. I think that you were asked on redirect about the proximity again, and I think we had talked a little bit about that. You had talked about 3 centimeters. I just want the record to reflect that when you talked about 3 centimeters, you held up two fingers, correct?
A. Uh-huh.
Q. And the space from the top to the bottom of those two fingers, that's what you're talking about as the amount of distance between them, correct?
A. Yeah, roughly.
MS. KIRKPATRICK: Roughly, okay. Nothing else, thank you.
THE WITNESS: Okay.

FURTHER EXAMINATION
BY MR. SNELL:
Q. And my follow-up is, do you hold -- continue to hold all your opinions in your reports and IMEs to a reasonable degree of medical and scientific certainty?
A. Yes, I do.
MR. SNELL: Thanks.
THE WITNESS: All right.
(Deposition recessed at 4:18 p.m.)
--oOo--

CERTIFICATE

I, SUSAN PERRY MILLER, Registered Diplomate Reporter, Certified Realtime Reporter, Certified Court Reporter and Notary Public, do hereby certify that prior to the commencement of the examination, CHRISTINA PRAMUDJI, M.D. was duly sworn by me to testify to the truth, the whole truth and nothing but the truth;

That pursuant to Rule 30 of the Federal Rules of Civil Procedure, signature of the witness was not reserved by the witness or other party before the conclusion of the deposition;

That the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

_____
Susan Perry Miller
CSR-TX, CCR-LA, CSR-CA
Registered Diplomate Reporter
Certified Realtime Reporter
Certified Broadcast Captioner
NCRA Realtime Systems Administrator
Certified LiveNote™ Reporter
Notary Public, State of Texas
My Commission Expires 03/30/2016

Dated: 24th of April, 2014

LAWYER'S NOTES

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